U.S. Department of Health and Human Services
National Institutes of Health
National Institute of Allergy and Infectious Diseases (NIAID)

RFP-NIH-NIAID-DAIDS-08-14
"Clinical Pharmacology Quality Assurance and Quality Control"

OMB Control Number 0990-0115

1. **OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.** http://www.fedbizopps.gov/

2. **SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1**
NOTE: The issuance of this solicitation does not commit the government to an award.

3. **Issue Date:**	4. **Due Date:** August 16, 2007	5. **Small Bus. Set-Aside:** [ ]Yes [X] No
May 11, 2007	**Time:** 4:00 P.M., Local Time	**8(a) Set-Aside:** [ ]Yes [X] No **NAICS: 541710** (See Part IV, Section L.)

6. **Just In Time:**	7. **Number of Awards:**	8. **Technical Proposal Page Limits:**
[ ] No [x] Yes (See Part IV, Section L.)	[X] Only 1 Award [ ] Multiple Awards	[ ] No [X] Yes (See Section J, Attachment 1, Packaging and Delivery of Proposal)

9. **Issued By:**	10. [x] **NIAID reserves the right to make awards without discussion.**	
Michelle L. Scala Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	11. **Options:** **[ ] No** **[X] Yes** (See Part IV, Section L.)	12. **Period of Performance:** **Base Period: 5/30/08 - 5/29/15**

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name: Lola Kellum **Phone:** 301-496-0612 **Fax:** 301-402-0972 **E-Mail:** mscala@niaid.nih.gov	**Name: Michelle Scala** **Phone:** 301-496-0612 **Fax:** 301-402-0972 **E-Mail: webstere@niaid.nih.gov**	Charles Grewe Director, Office of Acquisitions, NIAID Address (see Block 9.)

16. **COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.**

17. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Part III, SECTION J – Attachments)

18. **DELIVERY ADDRESS INFORMATION**

19. **Hand Delivery or Overnight Service:**	20. **U.S. Postal Service or an Express Delivery Service**
Lola Kellum, Contract Specialist Office of Acquisitions DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Lola Kellum, Contract Specialist Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with FAR 15.208 entitled "Submission, Modification, Revision, and Withdrawal of Proposals." FACSIMILE AND E-MAIL SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

13. DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR *(i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval)* WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

To develop a Clinical Pharmacology Quality Assurance and Quality Control (PQA/QC) Program that provides a technical and administrative infrastructure to ensure efficient planning, initiation, implementation, and management of PQA/QC activities in NIAID-sponsored clinical trial networks and collaborating study groups. It is expected that the Program will function at the domestic and international level in multiple laboratories to ensure the quality of NIAID-sponsored clinical pharmacology studies.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

(NOTE: The final contract will contain the cost provisions agreed upon by the Government and the offeror.)

a. The estimated cost of this contract is $.

b. The fixed fee for this contract is $. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is $.

d. Total funds currently available for payment and allotted to this contract are $, of which $ represents the estimated costs, and of which $ represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

e. It is estimated that the amount currently allotted will cover performance of the contract through .

f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of <u>any</u> item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

(See Attachment 7 for Advanced Understandings which will be included in any resultant contract.)

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated January 11, 2007, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. Please refer to Attachment 4, "Reporting Requirements and Deliverables" under this solicitation.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11 including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of any resultant contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Office of Acquisition, DEA
6700B Rockledge Drive, Room 3214
Bethesda, Maryland 20892 -7612

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable

condition.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, TBD is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at 6700B Rockledge Drive, Bethesda, MD 20817.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause 52.246-8, Inspection of Research and Development - Cost-Reimbursement (May 2001).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1 . DELIVERIES

a. Satisfactory performance of this contract shall be deemed to occur upon performance of the work described in the STATEMENT OF WORK Article C.1. in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the services specified in the Delivery Schedule which is described in SECTION C, ARTICLE C.2. of this contract. (Please refer to Attachment 4, "Reporting Requirements and Deliverables" under this solicitation).

b. Deliveries required by the contractor shall be made F.o.b. destination as set forth in FAR Clause 52.247-35, F.o.b. Destination, Within Consignees Premises (April 1984) and any specifications stated in SECTION D, PACKAGING AND MARKING AND SHIPPING, of this contract.

ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

Any contract awarded from this RFP will contain the following:
ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance

and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Contracting Officer hereby delegates the Project Officer as the Contracting Officer's authorized representative responsible for signing software license agreements issued as a result of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title

[To be specified in Contract]

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

(1) Invoices/financing requests shall be submitted as follows:

(a) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN266200411000C.)

ADB Contract No. (This is the 10 digit number that appears in the upper left

hand corner of the SF-26, i.e. N01-CO-41234.)

(b) An original and two copies to the following designated billing office:

Contracting Officer
Office of Acquisitions, DEA
National Institute of Allergy and Infectious Diseases , NIH
6700B Rockledge Drive, Room 3214, MSC 7612
BETHESDA MD 20892-7612

(2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 496 -0612.

ARTICLE G.4. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC 7540
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted .

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor

will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed has been approved by NIAID, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

The information below is a summary of the NIH Policy Announcement:

The contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.3. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.4. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

ARTICLE H.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b. , below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.6. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.7. PRIVACY ACT HHSAR 352.270-12 (January 2006)

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as an Attachment in SECTION J of this contract.

ARTICLE H.8. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (January 2006).

All information provided by the Provider or Project Officer shall be assumed to be confidential unless specifically identified as non-confidential in writing by the Project Officer. All materials supplied to the Contractor and all test results similarly are to be considered confidential.

ARTICLE H.9. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to clause 52.217-7 and 52.217-9 set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST PLUS FIXED FEE Article in SECTION B of this contract.

ARTICLE H.10. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, dated TBD is attached hereto and made a part of this contract.

(2) The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

(1) Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

(2) Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer/Contract Specialist shall be included as a contact for notification purposes at the following e-mail address:

[e-mail address for the Contracting Officer/Contract Specialist will be provided at time of award]

ARTICLE H.11. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b.

Public Law and Section No.*	**Fiscal Year***	**Dollar Amount of Salary Limitation***

c. Payment of direct salaries is limited to the Executive Level rate which was in effect on the date(s) the expense was incurred.

[*Applicable information to be included at award]

ARTICLE H.12. INFORMATION SECURITY

The Statement of Work (SOW) requires the contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf

a. Information Type

[ ] Administrative, Management and Support Information:

[x] Mission Based Information:

b. Security Categories and Levels

Confidentiality	Level:	**[x]** Low **[ ]** Moderate	**[ ]** High
Integrity	Level:	**[x]** Low **[ ]** Moderate	**[ ]** High
Availability	Level:	**[x]** Low **[ ]** Moderate	**[ ]** High
Overall	**Level:**	**[x] Low [ ] Moderate**	**[ ] High**

c. Position Sensitivity Designations

(1) The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

[ ] **Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI)**. Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

[ ] **Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI)**. Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[x] **Level 1: Non Sensitive (Requires Suitability Determination with an NACI)**. Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

(2) The contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: http://ais.niaid.nih.gov/forms/Suitability-roster.xls.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NIAID Information Technology Security Policies, Background Investigation Process" website: http://ais.NIAID.nih.gov.

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(3) Contractor/subcontractor employees shall comply with the HHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor/subcontractor employees may begin work under the contract after he contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c. (2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the contractor/subcontractor employee to work under the contract.

d. Information Security Training

The contractor shall ensure that each contractor/subcontractor employee has completed the NIH Computer Security Awareness Training course at: http://irtsectraining.nih.gov/ prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract.

The contractor shall maintain a listing by name and title of each contractor/subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by contractor/subcontractor staff shall be included on this listing. [The listing of completed training shall be included in the first technical progress report. (See Article C.2. Reporting Requirements.) Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.]

Contractor/subcontractor staff shall complete the following additional training prior to performing any work under this contract:

e. Rules of Behavior

Contractor Notification of New and Departing Employees Requiring Background Investigations

1. The contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer within five working days before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The government will initiate a background investigations on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.

2. New employees: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the government will determine the appropriate security level.

3. Departing employees:
-Provide the name, position title, and security clearance held by or pending for the individual.
-Perform and document the actions identified in the “Employee Separation Checklist”, attached in Section J, ATTACHMENTS of this contract, when a contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

The contractor/subcontractor employees shall comply with the NIH Information Technology General Rules of Behavior at: http://irm.cit.nih.gov/security/nihitrob.html.

f. Personnel Security Responsibilities

The contractor shall perform and document the actions identified in the "Employee Separation Checklist", attached and made a part of this contract, when a contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

(1) Contractor Agreement

The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

-18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
-18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
-Public Law 96-511 (Paperwork Reduction Act)

(2) Contractor-Employee Non-Disclosure Agreements

Each contractor/subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

i. Information System Security Plan

The contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

Following approval of its draft ISSP, the contractor shall update and resubmit its ISSP to the Project Officer every three years or when a major modification has been made to its internal system. The contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, *Guide to Developing Security Plans for Federal Information Systems*. (http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf). The details contained in the contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

Subcontracts: The contractor shall include similar information for any subcontractor performing under the SOW with the contractor whenever the submission of an ISSP is required.

ARTICLE H.13. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.270-19(b) (January 2006)

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the “Electronic and Information Technology Accessibility Standards” set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the “Access Board”) in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/.

The standards applicable to this requirement are [identified in the Statement of Work/listed below]:

ARTICLE H.14. ENERGY STAR REQUIREMENTS

Executive Order 13123, "Greening the Government Through Efficient Energy Management" and FAR 23.203 require that when Federal Agencies acquire energy using products, they select, where life-cycle cost-effective, and available, ENERGY STAR® or other energy efficient products.

Unless the Contracting Officer determines otherwise, all energy-using products acquired under this contract must be either an ENERGY STAR® or other energy efficient product designated by the Department of Energy's Federal Energy Management Program (FEMP).

For more information about ENERGY STAR® see http://www.energystar.gov/
For more information about FEMP see http://www.eere.energy.gov/

ARTICLE H.15. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause 352.270-6, Publications and Publicity incorporated by reference in SECTION I of this contract, the contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases , National Institutes of Health, Department of Health and Human Services, under Contract No. (TBD).

ARTICLE H.16. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.17. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS** (**1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489

Washington, D.C. 20026

ARTICLE H.18. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

1. Service Involving the Use of Information Technology

YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

2. Noncommercial Supply Items Warranty

YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS

The contractor warrants that each noncommercial item of hardware, software, and firmware delivered or developed under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the item documentation provided by the contractor, provided that all listed or unlisted items (e.g., hardware, software and firmware) used in combination with such listed item properly exchange date data with it. If the contract requires that specific listed items must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed items as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of any general warranty provisions of this contract provided that notwithstanding any provision to the contrary in such warranty provision(s), or in the absence of any such warranty provision(s), the remedies available to the Government under this warranty shall include repair or replacement of any listed item whose noncompliance is discovered and made known to the contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS

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_____

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(End of Clause)

3. Commercial Supply Products Warranty

YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

The contractor warrants that each hardware, software and firmware product delivered under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the product

documentation provided by the contractor, provided that all listed or unlisted products (e.g., hardware, software, firmware) used in combination with such listed product properly exchange date data with it. If the contract requires that specific listed products must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed products as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of the contractor's standard commercial warranty or warranties contained in this contract, provided that notwithstanding any provision to the contrary in such commercial warranty or warranties, the remedies available to the Government under this warranty shall include repair or replacement of any listed product whose non-compliance is discovered and made known to the contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS

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_____

_____

(End of Clause)

ARTICLE H.19. ANTI -LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.20. SHARING RESEARCH DATA

[The data sharing plan submitted by the contractor is acceptable/The contractor's data sharing plan, dated TBD is hereby incorporated by reference.] The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers

that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H.21. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

The Policy requests that beginning May 2, 2005, NIH-funded investigators submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html.

SECTION I - CONTRACT CLAUSES

THE FOLLOWING **ARTICLE I.1 GENERAL CLAUSE LISTING(S)** WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

General Clauses for a Cost-Reimbursement Research and Development Contract

The complete listing of these clauses may be accessed at:
http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clauses.jsp

ARTICLE I.2 AUTHORIZED SUBSTITUTION OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

ARTICLE I.1. of this SECTION is hereby modified as follows:

FAR Clauses **52.215-15, Pension Adjustments And Asset Reversions** (October 2004); **52.215-18, Reversion Or Adjustment Of Plans For Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, **52.215-19, Notification Of Ownership Changes** (October 1997), are deleted in their entirety.

Alternate IV (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications** (October 1997) is added.

FAR Clause **52.232-17, Interest** (June 1996) is applicable to this contract.

FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. ***[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]***

Alternate I (February 2002), of FAR Clause **52.232-25, Prompt Payment** (February 2002) is deleted.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

(1) FAR Clause **52.217-7, Option for Increased Quantity - Separately Priced Line Item** (March 1989).

"....The Contracting Officer may exercise the option by written notice to the Contractor within [INSERT THE PERIOD OF TIME IN WHICH THE CONTRACTING OFFICER HAS TO EXERCISE THE OPTION] ...."

(2) FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

(3) FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

(4) FAR Clause **52.224-2, Privacy Act** (April 1984).

(5) FAR Clause **52.227-14, Rights in Data - General** (June 1987).

(6) **Alternate II** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

Additional purposes for which the limited rights data may be used are:

(7) **Alternate III** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

Additions to, or limitations on, the restricted rights set forth in the Restricted Rights Notice of subparagraph (g)(3) of the clause are expressly stated as follows:

(8) FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

(9) FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).

(10) FAR Clause **52.230-6, Administration of Cost Accounting Standards** (April 2005).

(11) FAR Clause **52.237-3, Continuity of Services** (January 1991).

(12) FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

(13) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

(14) HHSAR Clause **352.223-70, Safety and Health** (January 2006).

(1) HHSAR Clause **352.270-5, Key Personnel** (April 1984).

(2) HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006)

(15) HHSAR Clause **352.270-8, Protection of Human Subjects** (January 2006).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

(1) **NIH (RC)-7, Procurement of Certain Equipment** (April 1984) (OMB Bulletin 81-16).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

a. FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees** (December 2004)

(a) Definition. As used in this clause--

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to--

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and
(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are provided as either attachments to this RFP or can be accessed through the weblinks provided below:

ATTACHMENTS TO THIS SOLICITATION: (The following documents are incorporated into this RFP:)

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 4:	Reporting Requirements and Deliverables	See Attachment Section at the end of this RFP
Attachment 5:	Additional Technical Proposal Instructions	See Attachment Section at the end of this RFP
Attachment 6:	Additional Business Proposal Instructions	See Attachment Section at the end of this RFP
Attachment 7:	Advance Understandings	See Attachment Section at the end of this RFP
Attachment 8:	Information Technology Systems Security – Prospective Offeror Non-Disclosure	http://rcb.cancer.gov/rcb-internet/forms/IT-security-nondisclosure.pdf

DOCUMENTS TO BE ATTACHED TO THE TECHNICAL PROPOSAL: (The following attachments must be completed, where applicable, and submitted with the Technical Proposal. They can be found at the electronic weblinks provided below and are, therefore not included as Attachments to this RFP.)

Title	Location
Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

DOCUMENTS TO BE ATTACHED TO THE BUSINESS PROPOSAL: (The following attachments must be completed, where applicable, and submitted with the Business Proposal. They can be found at the electronic weblinks provided below and are, therefore not included as Attachments to this RFP.)

Title	Location
Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/forms.htm
Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Disclosure of Lobbying Activities, OMB Form	http://rcb.cancer.gov/rcb-internet/forms/forms.htm

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INFORMATIONAL ATTACHMENTS: (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance. They can be found at the electronic weblinks provided below and are, therefore not included as Attachments to this RFP.)

Title	**Location**
Invoice/Financing Request Instructions–Cost-Reimbursement, NIH(RC)-1	http://rcb.cancer.gov/rcb-internet/forms/rc1.pdf
Privacy Act System of Records System of Records No. 09-25-0200 is applicable to this RFP.	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Procurment of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Roster of Employees Requiring Suitability Investigators	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the Online Representations and Certifications Application (ORCA) at: https://orca.bpn.gov/ and complete the Representations and Certifications; and

2. Complete, and include as part of your BUSINESS PROPOSAL, SECTION K which can be accessed electronically from the INTERNET at the following address:
   http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

p. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2004)]

(1) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", *"writing"*, or *"written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time*," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(2) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(3) *Submission, modification, revision, and withdrawal of proposals*. (a) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(b) The first page of the proposal must show--
- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(c) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(d) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(e) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(f) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(g) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(h) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(4) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(5) *Restriction on disclosure and use of data.* (a) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from

disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(b) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(c) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(6) *Contract award.* (a) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(b) The Government may reject any or all proposals if such action is in the Government's interest.

(c) The Government may waive informalities and minor irregularities in proposals received.

(d) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(e) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(f) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(g) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(h) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(i) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(j) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(k) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iv) A summary of the rationale for award.
(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

q. "**JUST IN TIME**"

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information during the initial evaluation of proposals. Certain documents will not longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy. The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision.

Annual Report. The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their final proposal revision.

Total Compensation Plan. The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a part of their final proposal revision.

Subcontracting Plan. The offeror's Small Business Subcontracting Plan shall **not** be submitted with the initial business proposal. Only those offerors included in the competitive range will be required to submit **an acceptable** subcontracting plan.

Cost/Pricing Information. The offeror's business proposal shall include the basic cost/pricing information specified in Section L.2.c.(1) of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. [The information may also include submission and certification of cost or pricing data.]

r. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.

(2) The small business size standard is 500.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

s. **TYPE OF CONTRACT AND NUMBER OF AWARDS**

It is anticipated that one award will be made from this solicitation and that the award will be made on/about May 30, 2008.

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement type contract completion with a period of performance of seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

t. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 7.85 full time equivalents (FTEs) per year for the base period and 1.02 full time equivalents per year for the options. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

u. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

v. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

w. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors are specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

x. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

y. **SERVICE OF PROTEST** - FAR 52.233-2 (SEPTEMBER 2006)

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Charles Grewe, Director
Office of Acquisitions, DEA
National Institute of Allergy and Infectious Diseases
6700B Rockledge Drive, Room 3214, MSC 7612
BETHESDA MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

z. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70 (January 2006)

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the Attachment 1 entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD.)

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY). However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Part IV, Section M of this RFP.

(7) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(8) **Standards for Privacy of Individually Identifiable Health Information**

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

(9) **Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)**

Under the provisions of the Rights in Data General clause (52.227-14), contractors must seek permission to establish a copyright for software and associated data generated under a contract. As a general rule, permission is normally granted provided, a paid-up, world-wide, irrevocable, nonexclusive license to the government is provided. This is to advise offerors that for this project, the government intends to assert additional copyright permissions under this contract. [The scope of the Government's interest in the copyright will be determined during negotiations.]

(10) **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(11) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

(12) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

(13) **Institutional Management of Conflicting Interests**

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(14) Past Performance Information

a) Offerors shall submit the following information as part of their business proposal.

A list of the last five contracts completed during the past three years and the last three contracts awarded, curently being performed, that are similar in nature to the solicitation workscope. Contrats listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any subcontract over $650,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b) The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(15) **Electronic and Information Technology Accessibility HHSAR 352.270-19(a) (January 2006)**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

(16) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

o) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).

p) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

c) Order of Precedence - Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

b. TECHNICAL PROPOSAL INSTRUCTIONS

NOTE: Offerors are advised to also refer to the information included in Attachment 5, Appendix A - Additional Technical Proposal Instructions.

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Project Objectives, NIH-1688-1**

The offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an **Institution of Higher Education:** The form MUST be completed in its entirety.
- For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, **"INSTRUCTIONS:"**

b) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

c) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in SECTION M - Evaluation Factors for Award of this solicitation.

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain

how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

IMPORTANT NOTE TO OFFERORS: The following paragraphs [(5) through (7) shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

(5) **Human Subjects**, HHSAR Provision 352.270-8(a) (January 2006)

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (MARCH 2005)

(a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The OpDiv will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OHRP, (telephone: 301-496-7005), is recommended.

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. The contracting officer will direct the offeror/contractor to the OHRP IRB Registration and Assurance Filing website, found at http://www.hhs.gov/ohrp/ or to the physical address if the offeror/contractor cannot access the Internet. HHS regulations for the protection of human subjects may be found at:
http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html

(f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory

requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

(6) **Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.

- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.

- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(7) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. You may download the information at this site at no cost and modify it, if desired. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at

http://www.centerwatch.com/order/pubs_profs_protect.html.

In addition, the NIAID sponsors an online training course at:

http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp.

If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

(8) **Sharing Research Data**

*[Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.]*

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

[If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.]

(9) **Information Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, "INFORMATION SECURITY."

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source. The National Institute of Standards and Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal information system and its information.

The Statement of Work (SOW) requires the successful offeror to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies the following requirements apply to this solicitation:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf

(a) Information Type

[ ] Administrative, Management and Support Information:

[x] Mission Based Information:

(b) Security Categories and Levels

Confidentiality	Level:	**[x]** Low	**[ ]** Moderate	**[ ]** High
Integrity	Level:	**[x]** Low	**[ ]** Moderate	**[ ]** High
Availability	Level:	**[x]** Low	**[ ]** Moderate	**[ ]** High

Overall Level: [x] Low [ ] Moderate [ ] High

(c) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each contractor (including subcontractor) employee that the successful offeror proposes for work under the contract. For proposal preparation purposes, the following designations apply:

[ ] Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI). Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

[ ] Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[x] Level 1: Non Sensitive (Requires Suitability Determination with an NACI). Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

Upon award, the contractor will be required to submit a roster of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a federal information system(s). The Government will determine and notify the Contractor of the appropriate level of suitability investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: http://ais.nci.nih.gov/forms/Suitability-roster.xls

Upon receipt of the Government's notification of applicable Suitability Investigations required, the contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NIAID Information Technology Security Policies, Background Investigation Process" website: http://ais.niaid.nih.gov.

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(d) Information Security Training

HHS policy requires contractors/subcontractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor/subcontractor employee has completed the NIH Computer Security Awareness Training course at: [insert link for course] prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer. Additional security training requirements commensurate with the position may be required as defined in NIST Special Publication 800-16, Information Technology Security Training Requirements (http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf). This document provides information about information security training that may be useful to potential offerors.

(e) Offeror's Official Responsible for Information Security

The offeror shall include in the "Information Security" part of its Technical Proposal the name and title of its official who will be responsible for all information security requirements should the offeror be selected for an award.

(f) Draft Information System Security Plan

The offeror must include a draft Information System Security Plan (ISSP) using the current template in Appendix A of NIST SP 800-18, Guide to Developing Security Plans for Federal Information Systems (http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf). The details contained in the offeror's draft ISSP must be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels.

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW with the offeror whenever the submission of an ISSP is required.

Note to Offeror: The resultant contract will require the draft ISSP to be finalized in coordination with the Project Officer no later than 90 calendar days after contract award. Also, a contractor is required to update and resubmit its ISSP to NIH every three years following award or when a major modification has been made to its internal system.

(g) References

(1) Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf
(2) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(3) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/

The following NIST publications may be found at the following site: http://csrc.nist.gov/publications/
[Note: The search tool on the left side of this page provides easy access to the documents.]

(4) NIST Special Publication 800-16, Information Technology Security Training Requirements; and Appendix A-D
(5) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
(6) NIST SP 800-26, Revision 1, Computer Security
(7) NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems
(8) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and
Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D
(9) NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
(10) FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
(11) FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

c. BUSINESS PROPOSAL INSTRUCTIONS

(20) **Basic Cost/Price Information**

NOTE: Offerors are advised to also refer to the information included in Attachment 6, Appendix B - Additional Business Proposal Instructions and Uniform Cost Assumptions.

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(21) **Proposal Cover Sheet**

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;

4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(22) **Information Other than Cost or Pricing Data**

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $650,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

(23) **Salary Rate Limitation in Fiscal Year 2007**

Offerors are advised that pursuant to P.L. ******, no NIH Fiscal Year 2006 (October 1, 2006 - September 30, 2007) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. ****** applies only to Fiscal Year 2007 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. ****** states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of Executive Level I*."

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/06tables/indexSES.asp

***Note to Offerors:** The current Fiscal Year Executive Level I Salary Rate should be adhered to in the*

preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year 2007 Executive Level I Salary rates.

**********Pending Passage of Legislation.*

(24) **Small Business Subcontracting Plan**

This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.

If the proposed contract exceeds a total estimated cost of $550,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $550,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

23% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(25) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in

unrestricted competitive acquisitions expected to exceed $550,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). TheNAICS codes can be found at: http://www.sba.gov/size

The Department of Commerce website for the annual determination for NAICS codes* is: http://www.arnet.gov/References/sdbadjustments.htm.

**Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

*Note: FAR Subpart 9.6 defines “Contractor team arrangements” to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(26) **Total Compensation Plan**

a) **Instructions**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.]

1) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors [included in the competitive range will be required to/as a part of their business proposal] will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

2) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

3) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b) **Evaluation**

1) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(27) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(28) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks,

office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

d) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

f) **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(29) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(30) **Proposer's Annual Financial Report**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.]

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(31) **Representations and Certifications - SECTION K**

One copy of SECTION K (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor. SECTION K can be found at:
http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

(32) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.]

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

a. **GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical , cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government intends to make an award to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

b. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH Policy requires:

(1) **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation in the proposed research plan, or provide sufficient information on the research subjects to allow a determination by NIAID that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

(2) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:

    - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
    - overriding factors dictate selection of subjects); or
    - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:

    - inclusion of those groups would be inappropriate with respect to their health,;or
    - inclusion of those groups would be inappropriate with respect to the purpose of the research.

- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated “unacceptable” (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or

"acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

(3) **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

If the information provided in your proposal about the inclusion of children is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

c. **MANDATORY QUALIFICATION CRITERIA**

Listed below are mandatory qualification criteria. The offeror shall include all information which documents and/or supports the qualification criteria in one clearly marked section of its proposal that address a particular mandatory qualification.

The qualification criteria establishes conditions that must be met at the time of receipt of Final Proposal Revisions (FPRs) by the Contracting Officer in order for your proposal to be considered any further for award.

Offerors must be CLIA-certified, with CLIA-certified bioanalytical and analytical laboratories/facilities. Offerors must submit with the application copies of the current CLIA certificates. Any subcontractor, who will conduct proficiency testing projects, as specified in the SOW, must meet the same mandatory qualification criteria and must provide the same documentation as required from the offeror.

d. **EVALUATION OF OPTIONS**

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options. (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

e. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy. If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

f. **TECHNICAL EVALUATION CRITERIA**

OFFEROR(S) AND REVIEWERS ARE ADVISED TO REFER TO APPENDIX A - Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATON RELATED TO THE PREPARATION AND EVALUATION OF PROPOSALS.

Technical Proposals submitted in response to this RFP will be evaluated based on the factors listed below. Proposals will be judged solely on the written material provided by the offeror and the information gathered by the Contracting Officer regarding past performance. It is anticipated that one award will be made as a result of this acquisition.

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERIA	**WEIGHT**
1. **Technical Approach**	**60 points**
a. Comprehensiveness and feasibility of the approaches and scientific soundness of the operating procedures to establish maintain and periodically execute Proficiency Testing (PT) Programs for pharmacology assays, including characterization and distribution of PT and QC samples, distribution of instructions, analysis of results from Sites, reporting results, and monitoring Site performance.	
b. Comprehensiveness and feasibility of the approaches and scientific soundness of the methods and operating procedures to acquire, characterize, store, document, and disburse analytical grade reference standards (AGRS)/reference drug powder, PT and QC samples, and other reagents.	
c. Comprehensiveness and feasibility of the approaches and scientific soundness of the analytical and bioanalytical methods to develop, validate, and implement pharmacology assays.	
d. Comprehensiveness and feasibility of the approaches and scientific soundness of	

the methods to conduct on-site laboratory inspection and audits.

e. Comprehensiveness and feasibility of the approaches and scientific soundness of the educational methodologies to train Site staff in PT and in the conduct of clinical pharmacology studies.

2. **Project Management** **15 points**

a. Evidence of organizational experience of the Contractor and its subcontracts in supporting the conduct of studies similar to those requested by the RFP, including a workable administrative structure, and an experienced QC Unit; soundness of the staffing plan and management for the conduct of the projects, including the clarity and appropriateness of assigned roles, time commitment, lines of authority, and adequacy of back-up staffing.

b. Adequacy of plans for developing, distributing and maintaining SOPs, policies, guidelines and user manuals; adequacy and soundness of the proposed list of organization SOPs, the sample SOP, procedures for staff training in SOPs, and plans for compliance with all safety guidelines and regulations including training and monitoring of personnel for exposure to infectious and hazardous reagents, as applicable to the Contractor and its subcontracts.

c. Adequacy of plans for maintaining and updating computerized data management systems to support the acquisition, testing, storage and disbursement of PT and QC samples, the development, validation and implementation of assays, laboratory staff training, on-site laboratory inspection and audits, and PT, and to capture Site capability and performance.

d. Adequacy of plans for communicating with NIAID Project Officer and the NIAID Contracting Officer.

e. Adequacy of plans for maintaining confidentiality of data.

f. Adequacy of plans to provide services to Sites added to the PQA/QC Program, should the Option be exercised, including PT services, site assistance and training; ability to recruit qualified personnel in a timely manner.

3. **Personnel** **15 points**

a. Principal Investigator (PI)

Documented availability of the PI and adequacy of scientific credentials in clinical pharmacology (e.g. Pharm D., M.D.); evidence of experience in supervising an inter-disciplinary team of scientists in the management and coordination of studies similar to those requested by the RFP; demonstrated ability to hire and deploy staff for projects that reflects flexibility and responsiveness to changing needs; demonstrated ability to implement plans required by the addition of Sites to the PQA/QC Program.

b. Project Manager

Documented availability, experience and qualifications in the management and coordination of multiple tasks or projects, customer service, and laboratory trouble-shooting; demonstrated ability to oversee and manage additional Sites in the PQA/QC Program

c. Professional and Technical Personnel

Documented availability, experience and qualifications of other professional and

technical staff in the area of pharmacological methodologies, bioresearch monitoring, statistical analyses, software systems management, and financial management; documented experience in the management of hazardous material shipments; documented experience of the personnel to perform team-oriented studies of a similar nature to those requested within the Statement of Work.

4. **Facilities, Equipment and Resources** **10 points**

1. Documented availability and adequacy of facilities to support and conduct studies required in the Statement of Work in compliance with CLIA and other applicable federal, state and local regulations, and adequacy of the floor plan indicating where work will be performed, list of equipment dedicated to the project, computers and IT resources for the life of the contract.

2. Documented security of the physical facility and of data and computerized systems; adequacy of emergency back-up measures; adequacy of the plan to comply with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and hazardous reagents.

3. Documented adequacy of the resources and facilities required to provide services to additional Sites, should the Options be exercised.

TOTAL: **100 points**

g. **PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgement by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

h. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachments applicable to this RFP as specified in SECTION J - List of Attachments

PACKAGING AND DELIVERY OF THE PROPOSAL

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals.

SUBMISSION OF PROPOSALS BY FACSIMILE OR E-MAIL IS **NOT** ACCEPTABLE.

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:
"**RFP NO. NIH-NIAID-DAIDS-08-14**
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. PAPER COPIES and CD-Rom to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Lola Kellum Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Lola Kellum Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

C. NUMBER OF COPIES:

TOTAL PAGE COUNT DOES NOT INCLUDE: Title and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section.

PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES.

FORMATTING AND LAYOUT:
Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals.

Documents submitted using Adobe .pdf shall be submitted using a .pdf searchable format.

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).
- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

CREATING AND NAMING ELECTRONIC FILES:

1. A separate CD should be submitted for the Technical Proposal and Business Proposal information. *Offerors who submit both Technical and Business Proposals on the same CD will be required to resubmit them on separate CDs.*

2. It is requested that the Technical Proposal be submitted as one document.

   Note: if multiple files are submitted for the either proposal, please include the name of the section in the file name.

   EXAMPLE: XYX Company-08-33-Technical-Approach-6-16-07

3. CDs should be named using the following format:

   Technical Proposal: ***Company name-RFP number-technical-date***
   Business Proposal: ***Company name-RFP number-business-date***

THE NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS REQUIRED OF EACH PART OF YOUR PROPOSAL ARE AS SPECIFIED BELOW.

PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

OFFERORS MUST CERTIFY THAT THE INFORMATION IN THE PAPER AND ELECTRONIC COPIES IS EXACTLY THE SAME.

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Six (6) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	**Not to Exceed 250 pages (inclusive of all Attachments and Appendices)**
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Business Proposal	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.**	N/A

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-08-14
RFP Title: Clinical Pharmacology Quality Assurance and Quality Control

Please review the attached Request for Proposal. Furnish the information requested below and return this page by no later than **July 16, 2007**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
OA, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

Attn: Lola Kellum
RFP-NIH-NIAID-DAIDS-08-14
FAX# (301) 402-0972
Email: mscala@niaid.nih.gov

STATEMENT OF WORK
CLINICAL PHARMACOLOGY QUALITY ASSURANCE AND QUALITY CONTROL
RFP NIH-NIAID-DAIDS-08-14

BACKGROUND AND INTRODUCTION

The Division of Acquired Immunodeficiency Syndrome (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, was formed in 1986 to address the national research needs created by the advent and spread of the HIV/AIDS epidemic. Specifically, the Division's mission is to increase basic knowledge of the pathogenesis, natural history, and transmission of HIV disease and to support research on detection, treatment, and prevention. DAIDS accomplishes this through planning, implementing, managing, and evaluating programs in (1) fundamental basic research, (2) discovery and development of therapies for HIV infection and its complications, and (3) discovery and development of vaccines and other prevention strategies.

The purpose of this solicitation is to award a contract to develop a Clinical Pharmacology Quality Assurance and Quality Control (PQA/QC) Program that provides a technical and administrative infrastructure to ensure efficient planning, initiation, implementation, and management of PQA/QC activities in NIAID-sponsored clinical trial networks and collaborating study groups. It is expected that the Program will function at the domestic and international level in multiple laboratories to ensure the quality of NIAID-sponsored clinical pharmacology studies.

Many NIAID-sponsored multi-site clinical trials of antiretroviral therapies include pharmacologic sub-studies requiring that drug levels be measured in several laboratories using different analytical methods. These methods must meet regulations of current Good Laboratory Practice (cGLP) and current Good Clinical Practice (cGCP).

A PQA/QC Program currently exists, as a grant, within the DAIDS-funded AIDS Clinical Trial Group (ACTG) and the International Maternal Pediatric Adolescent AIDS Clinical Trials network (IMPAACT) to support nine (9) US and one (1) non-US pharmacology laboratories. There is now a need to fund this Program as a contract. Laboratories supported by the PQA/QC Program shall hereinafter be referred to as Sites.

The new PQA/QC Program will operate in compliance with regulations of cGCP, cGLP and Clinical Laboratory Improvement Amendments of 1988 (CLIA), as well as other applicable federal, state, and local regulations. The number of participating Sites is expected to increase from ten (10) in the first year of the contract to sixteen (16) by the end of the contract period. This increase will occur through the exercise of options to expand the contract. Study Groups that will benefit from this resource include: the AIDS Clinical Trial Group (ACTG); the International Maternal Pediatric Adolescent AIDS Clinical Trials network (IMPAACT); the Microbicide Trials Network (MTN); the HIV Vaccine Trial Network (HVTN); and the HIV Prevention Trials Network (HPTN) (http://www3.niaid.nih.gov/news/newsreleases/2006/leadership.htm).

SCOPE

The scope of activities to be carried out under this contract include: 1) periodic execution of proficiency testing to evaluate the Site performance of pharmacology assays to measure antiretroviral and anti-opportunistic infection drugs and microbicides; 2) development and validation of pharmacology assays for implementation at Sites; 3) acquisition, characterization, storage, documentation and distribution of analytical grade reference standards (AGRS)/reference drug powder, QC materials and reagents; 4) training of Site staff in proficiency testing and in the conduct of clinical pharmacology studies; 5) on-site inspections and audits; 6) dissemination of technical and scientific data; and 7) maintenance of computerized systems to track PQA/QC Program activities.

TECHNICAL REQUIREMENTS

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment and facilities not otherwise provided by the Government as needed to perform the statement of work set forth below.

I. SUMMARY OF MAJOR FUNCTIONS

A. Proficiency testing (PT) program
B. Assay development, validation and implementation
C. Acquisition, characterization, storage, documentation, and disbursement of QC materials
D. Training
E. Laboratory inspections and audits
F. Dissemination of PQA/QC technical and scientific data
G. Maintenance of computerized data management systems
H. Project management
I. Initial and Final transition
J. Options

II. SPECIFICATION OF TASKS

A. PROFICIENCY TESTING (PT) PROGRAM

The Contractor shall develop a Pharmacology PT Program to conduct performance assessment of Sites. The core elements of this Program are:

1. Quality Assurance (QA) Standards for Executing PT

The Contractor shall develop a framework of Standard Operating Procedures (SOPs), or manuals, for executing the Pharmacology PT Program, in compliance with CLIA regulations and other applicable federal, state, and local regulations. This information must be immediately available and adhered to by all authorized Contractor staff.

2. PT Samples

For each Site specified by the Project Officer, the Contractor shall provide coded (unknown to Sites) PT samples, such as protease inhibitors, at intervals specified by the Project Officer. PT samples shall be prepared and provided to Sites as follows:

a) Acquire, confirm, test, aliquot, and store AGRS/reference drug powder.
b) Prepare and provide Sites with PT samples that include:

   i. low, medium, and high concentrations of each drug (in blank human plasma) that span the expected therapeutic range of the drug;
   ii. low, medium, and high concentrations of each drug (in blank human peripheral mononuclear cell (PBMC) extracts that span the therapeutic range and class of the drug; and
   iii. blank human plasma and/or human PBMC extracts.

3. Instructions for PT

The Contractor shall provide Sites with instructions, via written correspondence or email, including:

a) registration information and forms;
b) use of PT samples in assays (e.g., samples are tested along with patient samples and treated as if patient samples);
c) transport and storage of PT samples at the Sites;
d) method and format of PT performance and reporting; and
e) deadlines for registration and reporting PT results.

4. PT Results

The Contractor shall:

a) Receive the Site's PT results (via fax and with signatures) and information on methods of analysis and sample processing.
b) Verify the accuracy and completeness of PT results.
c) Analyze the results and determine successful Site performance based on acceptance criteria for drug measurements (within ± 20 percent of the target value). Evaluation factors shall be in compliance with applicable CLIA requirements.
d) Provide, via electronic mail, to each Site its Site-specific PT report, and to the Project Officer, four (4) weeks following data receipt from Sites.

5. Feedback to Sites and Follow-up

The Contractor shall discuss the final PT results with the Site in conference calls, and follow-up with corrective actions taken by the Site in the event of problems.

B. ASSAY DEVELOPMENT, VALIDATION, AND IMPLEMENTATION

The Contractor shall conduct projects related to assay development, validation, and implementation, in compliance with cGLP (21 CFR part 58), and applicable federal, state, and local regulations. Each completed project shall require submission of a Project Report to the Project Officer and relevant Study Group(s), as detailed in the Reporting Requirements and Deliverables section of the Contract. All such reports shall be cross-referenced in the Quarterly Progress Report.

1. Assay Development

Upon the Project Officer's approval, and collaborating with the participating Site, the Contractor shall:

a) Prepare and provide Sites with QC samples to assist in development of new assays (Sites are responsible for communicating their QC sample needs to the Project Officer).
b) Develop assays for the measurement of intracellular drug levels, multiple drug levels in different biomatrices, and investigational new drugs and drug metabolites.
c) Develop assays for drug stability and protein binding ability.
d) Develop assays to improve and refine the process of sampling, sample processing, and recovery.
e) Develop immunoassays for drugs.
f) Develop, review and finalize SOPs and QA documents for the collection, handling, processing and storage of samples used for drug assays, and for assay development.

2. Assay Validation

The Project Officer will give the Contractor one (1) month advance notice about the need to conduct assay validation projects. The Contractor shall:

a) Review and evaluate assay validation/re-validation reports (AVR) submitted by the participating Sites.
b) Notify the Site whether the AVR is approved, approved with required minor revisions, or pending approval with further supporting data, within one (1) to two (2) weeks of the completion of the AVR review.
c) Validate new assays, and re-validate existing assays if necessary.
d) Prepare final AVRs.
e) Develop, review, and finalize SOPs for assay validation and re-validation.

3. Assay Implementation

The Contractor shall:

a) Transfer newly validated assays to Sites. Upon the request of the Project Officer, the Contractor will be given three (3) months advance notice about the need to conduct and transfer such assays.
b) Minimally twice a year, review tracking reports/data from multi-site PK studies collected via the Laboratory Data Management System (LDMS®) (https://www.fstrf.org/ldms/).
c) Identify deviations/errors in external QC results and within-form discrepancies based upon assays, study type, study duration, and Site.
d) Inform the Site, the Study Group, and the Project Officer of unexpected, unacceptable high error/discrepancy rates occurring in the clinical trials, as soon as this data is available.
e) Assist the Site in initiating and implementing QA activities to correct errors.
f) Evaluate the corrective actions taken by Sites to remedy errors, and monitor the implementation of the recommended actions.
g) Develop, review and finalize SOPs, QA documents, and guidance documents for assay implementation.

C. ACQUISITION, CHARACTERIZATION, STORAGE, DOCUMENTATION, AND DISBURSEMENT OF QC MATERIALS

1. Acquisition of AGRS/Reference Drug Powder and QC Reagents

The contractor shall:

a) Acquire one of the following three types of AGRS/reference drug powder:

i. certified AGRS (e.g., USP reference standard);
ii. reference drug powder from commercial sources; and
iii. reference drug powder from non-commercial establishments (e.g., NIH AIDS Research and Reference Reagent Program).

b) Obtain AGRS/reference drug powder with relevant material safety data sheets (MSDS) and certificates of analysis (COAs).
c) Acquire biomatrices (e.g., serum, plasma, cell extracts, milk, urine, and semen) of human origin, which contain no personal identifying information, from either commercial or noncommercial sources; and chemical reagents.
d) Comply with FDA requirements for AGRS/reference drug powder. Comply with all applicable regulations for the use of human tissue samples in research, and comply with HIPAA and Privacy Act requirements.

2. Characterization of AGRS/Reference Drug Powder and Preparation of PT/QC Samples

a) For commercially and non-commercially supplied AGRS/reference drug powder, the Contractor shall:

i. Record and track changes of lots during method operation studies.
ii. Recertify each lot of ARGS/reference drug powder every six months.

b) Prepare (e.g., dilute, aliquot, and label) PT and QC samples, and other QC reagents for Sites.

3. Determination of Stability of PT/QC Samples and Reagents

The Contractor shall determine the stability of PT/QC samples and reagents, and compile stability data (e.g., in various matrix types, ranges of concentration tested, number of replicates, storage condition, and other conditions), and provide Sites with the information.

4. Storage of AGRS/Reference Drug Powder, PT/ QC Samples, and Reagents

The Contractor shall store characterized AGRS/reference drug powder, aliquots of PT and QC samples, and reagents under conditions that ensure continued activity and stability of materials. The Contractor shall test effects of length of storage, storage temperature, and shipping temperature and time on stability of these materials.

5. Shipment of AGRS/Reference Drug Powder, PT/QC Samples, and Reagents

Upon Project Officer's approval, the Contractor shall ship AGRS/reference drug powder, PT and QC samples, and reagents to specified US and non-US Sites under appropriate shipping conditions (e.g., temperature monitoring) and in accordance with the International Air Transport Association (IATA) (http://www.iata.org/index.htm) and International Civil Aviation Organization (ICAO) (http://www.icao.int/) dangerous goods shipping regulations and other relevant shipping regulations. Additionally, the Contractor shall:

a) Execute agreements with receiving institutions regarding relevant standards for safe handling and authorized use and discard of AGRS/reference drug powder, samples, and reagents.
b) Arrange overnight (or fastest possible) delivery of shipments to the Sites.
c) Obtain the appropriate interstate and foreign shipping licenses and permits for transporting biohazard materials.
d) Coordinate the shipments of AGRS/reference drug powder, PT and QC samples, and reagents to the Sites, including notices of incoming shipments.

6. Safety and Health

The Contractor shall provide its personnel with protective garments, equipment, training and sufficient monitoring to assure safe handling of potentially hazardous and infectious materials in compliance with all applicable health and safety regulations while conducting the work set forth herein, and adhere all safety and health regulations in accordance with HHSAR 352.223-70.

7. Facilities, Equipment and Other Resources

The Contractor shall provide facilities, equipment and other resources to adequately accommodate acquisition, characterization, storage, distribution, and disposal of potentially hazardous materials, and to support studies of assay development, validation, and implementation. The Contractor's analytical testing facilities shall be CLIA-certified and in compliance with cGLP and cGCP and applicable federal, state and local regulations.

The Contractor shall provide emergency backup measures to ensure the stability of samples and reagents, and security measures to ensure protection of the facility and equipment against damage by fire, theft, vandalism, invasion of privacy, and intrusion by unauthorized personnel.

8. Documentation of AGRS/Reference Drug Powder, PT and QC Samples, and Reagents

The Contractor shall summarize activities related to acquisition, characterization, storage and distribution of AGRS/reference drug powder, PT and QC samples, and reagents, in the Quarterly Technical Reports.

D. TRAINING

The Contractor shall:

1. Prepare and make available to Sites written and electronic PT training materials.
2. Prepare and make available to Sites written and electronic training materials for the implementation of clinical pharmacology studies.
3. Certify trainees, including study coordinators and nurses at clinical trial units (CTUs); post training information on the Contractor's Internet-enabled website.

4. Within one (1) month of training completion, submit Training Reports to the Project Officer.
5. Identify continuing education needs, especially for new assay development, validation and implementation; plan and organize workshops on those assays at the Contractor's Site or other suitable location. The Contractor shall provide the teaching staff and the materials required for "hands-on" training/demonstrations. The Contractor shall not be responsible for travel costs of participants.

E. LABORATORY INSPECTIONS AND AUDITS

The Contractor shall provide a comprehensive QA program to inspect the Sites conducting clinical pharmacology testing, and audit clinical pharmacology studies to determine the degree of compliance with CLIA, cGCP, cGLP, and other applicable federal, state, and local regulations of the Sites. The Project Officer will identify Sites and studies requiring inspection and audit, and will give the Contractor one (1) month advance notice. Inspections and audits are expected to take two (2) to five (5) days. The Contractor shall:

1. Conduct On-Site Inspections that include:

    a) patient test management systems;
    b) organization, practices, and qualifications of personnel;
    c) procedures utilized, the QA unit, facilities, storage space for specimens, and equipment;
    d) QC materials and reagents, and other testing articles;
    e) protocol adherence to clinical pharmacology studies and the conduct of clinical pharmacology testing/studies; and
    f) records and documents.

2. Conduct on-Site audits that include:

    a) a comparison of the Site's protocol, raw clinical and analytical data, records, and specimens against a Final Study Report;
    b) review of study records for quality to ensure that data are attributable, legible, contemporaneous, original and accurate;
    c) determination of any significant changes in the facilities, operations, and QA unit functions compared to those previously reported; determination of whether the equipment used is inspected, standardized, and calibrated prior to and during the testing;
    d) review of the remedial action taken if equipment malfunctioned, and ensuring that the Final Study Report addresses whether the malfunction affected the testing;
    e) determination whether approved SOPs exist during the conduct of the testing; and
    f) review of the Final Study Report for the Principal Investigator's dated signature and the QA unit statement.

3. Prepare and submit Site Inspection/Audit Finding Reports to the Site Principal Investigator, the Project Officer, and other relevant User Group(s) as specified by the Project Officer. The Contractor shall refer to: http://www.labcompliance.com/usersclub_preview/fda_483.htm, for further information about Inspection/Audit Report.

4. Review Sites' Corrective Action Reports within four (4) weeks after the reports are received, and provide appropriate follow-up action, such as conducting a re-inspection six (6) months after the Corrective Action Reports are received.

F. DISSEMINATION OF PQA/QC TECHNICAL AND SCIENTIFIC DATA

1. Publication and Presentation of Data

The Contractor shall:

a) Prepare, within three (3) months after study completion, materials/reports to support preparation of documents for IND/NDA and of scientific manuscripts for publication in peer-reviewed journals.
b) Present data at NIAID-sponsored meetings and at US and non-US scientific meetings.

2. Conference Calls and Meetings

The Contractor shall:

a) Participate in weekly phone calls that include the Project Officer, the Principal Investigator, the Project Manager, statistician and other personnel specified by the Contractor or the Project Officer.
b) Participate in monthly conference calls with Sites working on assay development and validation. When necessary, schedule conference calls, the cost of which will be charged to the contract.
c) Meet with Project Officer at periodic intervals (at least twice a year) to review progress, anticipated or existing problems, and to discuss the work to be performed, workload and accomplishment. The schedule and location of such meetings/Site visits shall be determined by the Project Officer.
d) Make facility and meeting arrangements for annual visits by the Project Officer and Contracting Officer to the Contractor's Site. Meeting arrangements shall be approved in advance by the Project Officer.

G. COMPUTERIZED DATA MANAGEMENT SYSTEMS

The Contractor shall maintain state-of-the-art software systems for data management in support of all PQA/QC activities, in compliance with "Secure One HHS" and regulations set forth in Final Rule 21 CFR 11 pertaining to research data and records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted. Any software used to capture or analyze data shall be designed in a format that will easily permit capture of assay results by the LDMS® for assays implemented in clinical trials and performed on patient specimens. The Contractor shall be responsible for the purchase of all general purpose ADP equipment and related maintenance agreements.

1. Computerized Tracking Systems

The Contractor shall provide computerized software systems to track:

a) PT data, including information about participating Sites, relevant dates, information about drugs used, panel scheme, assay systems used by Sites, statistical methods used to analyze PT results, Site performance and certification status, and corrective action.
b) Assay development and validation data, including testing Sites, tested analyte/drug, matrix, methods, and assay results and data analysis
c) AGRS, QC sample, and reagents, including source of materials, stability data and storage conditions.
d) Site-related information, including status of Site CLIA certification, Site inspection and audit dates, and Site publications in clinical pharmacology.

2. PQA/QC Website

The Contractor shall:

a) Develop, maintain and update an interactive Internet-enabled website for posting relevant, updated PQA/QC information.
b) Provide the Project Officer and his/her designee with read/print-only access to the database via the Contractor's website.

3. DAIDS Enterprise System

The Contractor shall provide Contractor-related PQA/QC information, specified by the Project Officer, to the DAIDS Enterprise System (Appendix C).

4. Electronic Communication

The Contractor shall:

a) Provide the capability to receive and transmit data files electronically via the LDMS® and to communicate electronically via secure e-mail with all Sites, the network Data Management Center (DMC), the DAIDS Enterprise System, and the Project Officer.
b) Provide and maintain a state-of-the-art software system for data management and expedited processing of selected high priority information and for ready transferal of data and complete system and data documentation to NIAID or other NIAID contracts at the direction of NIAID at any point during the contract. The system shall provide sufficient flexibility and accessibility to answer any inquiries in a timely manner, typically no more than one (1) business day.

5. Information Security (InfoSec)

InfoSec consists of:

a) Confidentiality – the prevention of unauthorized disclosure/use of information;
b) Integrity – the prevention of unauthorized modifications to information; and
c) Availability – ensuring the reliable and timely access to data or computing resources.

With input from NIAID and Office of Technology and Information System (OTIS) staff, the Contractor shall conduct a study of the InfoSec requirements for the entire project. The study shall include a definition of what the system is comprised of, such as the physical and logical description of the entire system including hardware, software, communications, InfoSec and other considerations, including:

a) privacy requirements of clinical pharmacology data;
b) physical and electronic security for hardware, software and communications; and
c) the requirement that all participants in the contract (subcontractors, NIAID staff, study Site investigators, etc) need to have a secure capability to communicate and exchange specific information in the case of a national disaster that could disrupt the ability to interact and exchange needed information.

6. System Security

System security shall meet NIH requirements (http://irm.cit.nih.gov/security/secplantemp.doc). The Contractor shall develop a security plan and submit it to NIAID within 60 business days after the effective date of the Contract, for Office of Technology and Information Systems (OTIS), NIAID approval. Additional information is also available at http://irm.cit.nih.gov/nihsecurity/NIH_System_C&A.htm. The Contractor shall implement and maintain security requirements for the data management to:

a) Ensure confidentiality of all subject or donor records (both hard copy and electronic).
b) Ensure security of data related to performance evaluation of participating Sites.
c) Provide security against anticipated risks, including loss of confidentiality of subject records and vital or catastrophic loss of study data or important software.

7. Systems Maintenance and Upgrade

a) Maintain and upgrade reliable and secured electronic communication linkages with NIAID, NIAID-sponsored remote DMC, Sites and investigators who send e-mail and share text and data files.
b) Management tools, computer systems, databases, documentation, data, and any other electronic files or items developed via this contract will remain the property of NIAID.

8. Information Technology (IT) Report

With input from NIAID subject matter experts, the Contractor shall study the Information Technology (IT) hardware, software, networking and security needs for the entire project and develop a report of IT requirements (including a complete IT security assessment). Part of this process shall include interaction with, and review by, OTIS staff to ensure alignment with NIAID IT operations, business processes, and documentation deliverables for the proposed IT infrastructure. The IT report's final recommendations shall include: IT architecture (network, security, server, implementation, and database), schemas, run books, processes, procedures, disaster recovery, failover, trouble shooting, implementation or system monitoring, and change control or management.

H. PROJECT MANAGEMENT

The Contractor shall provide a scientific, technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, management and completion of all contract activities, including activities carried out under subcontracts. This infrastructure shall include a Principal Investigator, a Project Manager, professional and technical personnel, and administrative staff. The Principal Investigator shall be responsible for overall project management and communications, tracking, monitoring and reporting of project status and progress, and the recommendation of modifications to project requirements and timelines. NIAID reserves the right to conduct independent audits of the Contractor and its subcontractors and expects that all records and staff will be available in response to site visits or study-specific audits by NIAID or its designee.

Projects will be assigned in writing by the Project Officer and will outline the background and basic needs of the proposed project. The Contractor shall not initiate or conduct studies using contract funds without prior approval by the Project Officer. Within ten (10) business days of receipt of a project assignment, the Contractor shall provide a written Project Plan to the Project Officer for approval. The Project Plan, describing the approach to the assignment, may be in outline form; however, it shall be of sufficient detail to clearly support the rationale for each step and the methods to accomplish the task. The Contractor shall specify the resources necessary to accomplish the request and document their availability with a timeline for accomplishing the assignment.

I. INITIAL AND FINAL TRANSITION

1. **Initial Transition**

The Project Officer will provide the Contractor with a copy of the Final Transition Plan from the existing PQA/QC Program that is funded by NIAID as part of a grant to the ACTG and to the IMPAACT networks. Existing PQA-related data will be transferred in the form of spreadsheets or transfer of entire database. Within ten (10) business days of receipt of Final Transition Plan, the Contractor shall provide an Initial Transition Plan and a Gantt chart for the receipt, storage, and assessment (as necessary) of all items being transferred from the existing PQA/QC Program. Upon written approval by the Project Officer, the Contractor shall complete the Initial Transition Plan within 20 business days of the approval.

Within ten (10) business days after contract award, the Contractor shall submit a contract-specific Information Security Plan for review and approval by NIAID, in compliance with "Secure One HHS."

2. **Final Transition**

The Contractor shall ensure an orderly transition to a possible successor Contractor prior to expiration of this contract.

a) Four (4) months prior to the completion of this contract, the Contractor shall provide to the Project Officer a draft plan that details the transition to a successor Contractor of all contract-related materials. These materials shall be organized and catalogued in sufficient detail to support an orderly transition to the successor Contractor. The Contractor shall work with the Project Officer and the Contracting Officer to refine and complete this plan, with a Final Transition Plan to be provided to the Project Officer two (2) months prior to the expiration date of the contract. The Final Transition plan shall include recommended steps with a detailed cost estimate to sustain the activities provided for in the contract during transition and shall include delivery to the NIAID or its designee by the expiration date of this Contract.
b) Contract-related items include:

   i. stored AGRS, PT samples, QC samples, and reagents. The Contractor shall perform calibration and lot-to-lot comparisons between AGRS, PT, QC samples, and reagents to be transferred to the successor Contractor;
   ii. all data files in computer readable format and software systems (with documentation and specifications) including systems for tracking PT and real-time assay validation data, AVRs, assay development research data, training records, records of Site inspection and audits, inventory data, and statistical analysis data (information shall be provided in electronic format and transferred in a secure manner as determined by the Project Officer with input from the Contractor);
   iii. laboratory/manufacturer correspondence files, SOPs, and archived activity files for incoming and outgoing shipments; and
   iv. Government Furnished Property (GFP), if applicable.

c) Notify all Sites as early as possible of the transition and provide schedules to the Sites for the transition, and instructions concerning any changes in testing schedules anticipated during the transition.

J. OPTIONS

1. The NIAID anticipates the potential need to provide services to additional Sites. The base portion of the contract consists of ten (10) Sites at the time of contract award. Over the course of the contract, the total number of Sites is expected to increase to 16 through the exercise of Options, at the discretion of the Government.

   Under the Option, the Contractor shall add one (1) Site to the PQA/QC Program. Sites may be added during contract years 2-7. The NIAID reserves the right to exercise more than one option per year, however, the total number of 'optional' Sites shall not exceed six (6) for the 7-year period of the contract. Under the Option, the Contractor shall provide the Site with the following contract services:

   a) Proficiency Testing;
   b) ARGS/reference drug powder and QC samples for the development, validation and implementation of assays; and
   c) Training.

2. Develop a plan for the necessary services called for by the Government's exercise of Options, including all tasks, staff, facilities, equipment, and other resources required to implement the Options and a timeline for completion of all tasks.

3. Based on the Project Officer's recommendation to implement the Option Plan, the Contracting Officer will authorize the exercise of each Option through a Modification to the contract. The Contractor shall begin the task within two (2) months of receiving the Modification.

[END OF STATEMENT OF WORK]

REPORTING REQUIREMENTS AND DELIVERABLES
CLINICAL PHARMACOLOGY QUALITY ASSURANCE AND QUALITY CONTROL
RFP NIH-NIAID-DAIDS-08-14

I. TECHNICAL REPORTS

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES. The Contractor shall provide the reports and deliverables specified below. All reports shall be submitted in electronic form as PC-formatted computer files in Microsoft Word™ and Microsoft Excel™ and/or searchable PDF format. Electronic versions shall be sent on CD or more current electronic data storage medium, by US mail or courier service. All reports shall be archived on CD or other appropriate media for surrender to the Government at the expiration of the Contract.

A. Quarterly Technical Progress Report

The first reporting period consists of the first full three (3) months of contract performance, including any fractional part of the initial month. Thereafter the reporting period shall consist of three (3) full calendar months. The Contractor shall submit copies of the Report on/before the 15th of the month following the end of each quarter. A Quarterly Technical Progress Report shall not be required when an Annual Technical Progress Report is due. Each Report shall include:

1. a cover page with:

    a. Contract number and title;
    b. period of performance being reported;
    c. type of report and period covered;
    d. Contractor's name and address;
    e. author(s);
    f. date of submission; and
    g. QA Statement and Signatures of QA Staff, if required.

2. an introduction covering the purpose and scope of the contract's effort pertaining to the period of the report;

3. summaries of activities for the quarter being reported upon as specified in the Statement of Work;

4. Proficiency Testing (PT) status including (SOW Task A):

    a. current number of participating Sites;
    b. summaries of Sites' PT performance assessment results and certification status;
    c. summary of problems, communication with Sites and corrective actions; and
    d. summaries of PT training of all participating Sites.

5. Project Reports that include assay development, validation and implementation reports shall be cross-referenced in the Quarterly Technical Progress Report. In addition, the following information shall be included (SOW task B):

    a. summaries relating to the number and type of assays developed and validated, and their implementation; and
    b. summary of any new and revised SOPs, QA documents, and reference materials.

6. AGRS/reference drug powder, PT and QC samples, and reagents available to Sites (SOW Task C):

a. summary of acquisition, characterization, storage and distribution data of AGRS/reference drug powder, and reagents, with an updated list of MSDS and Certificates of Analysis (COAs);
b. summary of stability data of PT samples and QC samples; and
c. shipment table of PT and QC samples, and reagents sent to Sites including quantity, date, and Site location.

7. Bioanalytical facilities and equipment (SOW Task C):

   a. freezer inventory including any retired and new purchases for AGRS/reference drug powder, PT and QC samples, and reagents;
   b. summary of maintenance reports for freezers, centrifuges, analytical instruments and facilities to include out-of-range findings and corrective actions; and
   c. summary of findings of laboratory inspections and audits to include problems encountered and corrective actions taken that could refer to the laboratory inspection.

8. Communication with the Project Officer (SOW Task F):

   a. summary of meetings/discussions with the Project Officer regarding issues relevant to the conduct of the contracted work;
   b. summary of work projected for the following quarter;
   c. a tracking table containing conference call issues, resolutions, and/or action items, by conference call date; and
   d. summary of semi-annual meetings with the Project Officer, provided every other Report.

9. Scientific Activities. This shall include a list of scientific meetings and conferences attended, a list of manuscripts published, submitted or in preparation, and a list of abstracts submitted for presentation or in preparation (SOW Task F).

10. Computerized data management systems (SOW Task G):

    a. summaries of computerized data management activities for PT; assay development, validation and implementation; AGRS/reference drug powder, and PT and QC sample tracking;
    b. summary of issues and solutions related to computer hardware and, software, computer facilities and LDMS®, as well as to the DAIDS Enterprise System;
    c. summary of issues and solutions related to system security, system maintenance and upgrade, and information security;
    d. summary of PQA activities updated and/or posted on an interactive, internet-enabled website;
    e. summary of electronic communication with Sites, data management centers, the DAIDS Enterprise System, and the Project Officer.

11. Personnel Report, which shall include name, title, percent effort and responsibility of each key scientific personnel who is working on the contract, as well as subcontractors and/or consultants. For each individual provide a brief summary of tasks performed during the quarter (SOW Task H).

B. Annual Technical Progress Report

The Annual Technical Progress Report shall include a summation of work accomplished in the preceding 12-month period and outline work currently in progress. Each Annual Technical Progress Report shall include a cumulative list of projects assigned and completed since the contract award date. It shall include a description of any current technical or administrative problems, their resolution, or the corrective action taken during the preceding 12-month period. It

shall include the last Quarterly Technical Progress Report and an Annual Table of Contents referring to previous Quarterly Technical Progress Reports. It shall contain a title page which follows the format and content described below for Project Reports. An Annual Technical Progress Report shall not be required for the period when the Final Report is due.

C. Final Report

The Final Report shall document and summarize the results of the entire contract period of performance. The Final Report shall contain a title page which follows the format and content described below for Project Reports. It shall be in sufficient detail to explain comprehensively the accomplished tasks, a brief description of any unfinished projects, and a status report on transition or shut down activities. The Report shall contain a cumulative list of submitted Project Reports and a cumulative list of assigned projects, covering the entire contract performance period. A draft of the Report shall be submitted for review by the Project Officer 30 days prior to the completion of the contract. The Final Report shall be submitted on or before the last day of the contract performance period.

D. Summary of Salient Results – (Form 1688-1)

The Contractor shall submit, with the Final Report, a summary of salient results detailing the important accomplishments from the contract during the performance of the contract.

II. TECHNICAL REPORTS DELIVERY SCHEDULE

Satisfactory performance of the contract is defined as satisfactorily performing the statement of work, including delivery of the following items:

Item	Type of Report	Initial Report Due	Recipients & Number of Copies	Subsequent Report Due
A.	Quarterly Progress Report	3 Months including any fractional part of the initial month after Effective Date of Contract	Original – CO 1 copy – PO	Due on or before 15 days following each quarter reporting period. Not due when Annual Technical Progress Report or Final Report are due.
B.	Annual Progress Report	Anniversary Date of Contract	Original - CO 1 copy - PO	Annually; due within 15 days after the anniversary date. Annual Report not due when Final Report is due.
C.	Final Report	30 days prior to Contract Expiration Date (CED)	Original - CO 1 copy – PO	Edited Final Report due on CED.
D.	Form 1688-1	At CED	Original - CO 1 copy – PO	

If the Contractor becomes unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer written notice at least ten (10) business days prior to the due date of anticipated delays with reasons therefore. The Contracting Officer and Project Officer must approve the extension in writing. A new delivery date must be established.

III. OTHER REPORTS/DELIVERABLES

A. PT Report

The Contractor shall provide a PT report to each Site and the Project Officer four (4) weeks following PT data receipt from Sites. The Report shall include:

1. participating Site contact information;
2. relevant dates (e.g., sample shipping and testing dates);
3. drug, drug class, drug concentration levels or amounts, and lot numbers of PT samples;
4. panel and round number, tube number(s), volume, number of aliquots of PT samples;
5. assay systems, e.g. HPLC-UV, HPLC-MS or immunoassay;
6. QC data, including standard inter- and intra-assay variability measures;
7. analysis of results, noting the statistical methodologies employed; and
8. PT performance and certification status of Sites.

B. Project Plans

Within ten (10) business days of project assignment by the Project Officer, a Project Plan, detailing how a particular study shall be approached, must be prepared and submitted to the Project Officer, as specified in SOW Task B. The Project Plan shall include contents listed below under the Project Reports. Additionally, the plan shall include a brief introduction to the task, proposed methods for addressing the task, anticipated problems and their possible resolution, and a general timeline for completion of the project. Data from these studies shall also be provided to the Project Officer on an ad-hoc basis when requested.

C. Project Reports

The Project Report shall detail the work performed on that Project. A project is defined as a discrete written request by the Project Officer for PQA/QC and related activities.

1. Assay Development, Validation, and Implementation Reports

Within 60 days following completion of data analysis, the Assay Development, Validation and Implementation Reports shall be submitted to the Project Officer and include:

a. an introduction describing the assigned task;
b. QA statement regarding dates of data review, audit and report, QA auditors signature, and in compliance with cGLP or CLIA regulations or not;
c. Table of Contents;
d. an assay development, validation, and implementation summary;
e. detailed information on specimen collection, QC sample preparation, shipment, dates of inventory and storage;
f. detailed stability data of QC samples;
g. list of reagents, chemicals, internal standard, and materials used;
h. list of instrument parameters and procedures used;
i. validation and assay implementation results, and a discussion section;
j. representative tables, regression spectra, chromatograms, and other charts and tables/tracings from instrument analyses;
k. literature references
l. method of protocol validation; and
m. amendment of re-validation of assays

2. Site Training Reports

Within 30 days of training completion, the Contractor shall submit Training Reports to the Project Officer. The Training Report shall include type of the training, participants'

information, date and duration, summary of the training and evaluation, and certification, as well as summary of employees' training records on safety issues.

3. Site Inspection and Audit Reports

Within 30 days following completion of Site inspection and audits, the Contractor shall submit the Site, the Project Officer, and the relevant User Group(s) Inspection/Audit Report. The Inspection/Audit Report shall include a notification letter and problems noted in the area of the inspection and audits.

4. PQA/QC Technical Data

Within three (3) months after study completion, the Contractor shall prepare material/reports to support preparation of IND/NDA documents, scientific manuscripts, and data to be presented at NIAID-sponsored meetings and at US and non-US scientific meetings.

D. Information Technology (IT) Plan and InfoSec Study

Draft a plan for the secure transfer, maintenance, and upgrade of data, hardware and software within ten (10) business days of the start of the contract, as specified in the SOW, Task I; draft a plan for the Information Technology Report and InfoSec study within 60 days of start of the contract.

E. Plan for Services to be provided by the NIAID's Exercise of a Contract Option.

This plan shall include staffing requirements, costs, and a description of work to be performed. The plan will be initiated if an option to expand the contract is exercised by the Contracting Officer.

F. Transition Plans

1. **Initial Transition Plan**

If applicable, within ten (10) business days of receipt of Final Transition Plan and other materials from the existing PQA/QC Program, the Contractor shall provide an Initial Transition Plan and a Gantt chart for the receipt, storage, and assessment (as necessary) of all items being transferred from the existing PQA/QC program. This plan shall include staffing requirements and a description of work during the transition.

2. **Draft Final Transition Plan**

Four (4) months prior to the expiration date of the contract, provide a draft Final Transition Plan which describes proposed procedures for an orderly transition to a subsequent Contractor or the NIAID, and the estimated cost.

3. **Final Transition Plan**

A Final Transition Plan shall be provided two (2) months prior to the completion date of the Contract.

G. A list of QA documents and SOPs and copies of SOPs and QA documents that detail the manner, in which the Contractor performed a specific type of assay, procedure, or function, will be requested from time to time.

H. Contract Completion

The Contractor shall deliver to the NIAID or its designee, by the completion date of this contract, stored AGRS/reference drug powder, PT and QC samples and reagents, inventory and software systems including software programs, labeled and inventoried paper files, and Government Furnished Property (GFP), if any.

IV. OTHER REPORTS DELIVERY SCHEDULE

Satisfactory performance of the contract is defined as satisfactorily performing the Statement of Work, including delivery of the following items:

Item	Type of Deliverable	SOW Ref.	Initial Report Due	Recipients & Number of Copies	Subsequent Reports Due
A.	PT Report	Task A	4 weeks following PT data receipt from Sites	1 copy - Site PI 1 copy – PO	After every PT round
B	Project Plans	Task B	Within 10 business days of the request for a Project Plan	1 copy - PO	
C.1	Project Report -Assay Development, Validation, and Implementation Reports	Task B	Within 60 days following completion of data analysis	1 copy - PO	As required
C.2	Project Report -Site Inspection and Audit Report	Task E	Within 30 days following completion of an inspection/audit	1 copy - Site PI 1 copy - PO 1 - Study Group	As required
C.3	Project Report - Site Training Reports	Task D	Within 30 days of a training	1 copy – PO	As required
C.4	PQA/QC Technical and Scientific Data	Task F	Within 3 months following completion of the study	1 copy - PO	
D.1	IT Plan	Task I	Within 10 business days after the effective date of the contract	1 copy - CO 1 copy - PO	
D.2	InfoSec Study	Task G	Within 60 business days after the effective date of the contract	1 copy - CO 1 copy – PO	
E.	Plan for the Exercise of a Contract Option	Task J	As required by PO	Original - CO 1 copy - PO	As required
F.1	Initial Transition Plan	Task I	10 business days after the effective date of the contract	Original - CO 1 copy - PO	Implementation 30 days after contract award
F.2	Final Transition Plan (Draft)	Task I	4 months prior to completion of the Contract.	Original - CO 1 copy - PO	
F.3	Final Transition Plan (Final)	Task I	2 months prior to completion of the Contract.	Original - CO 1copy - PO	
G.	A list of SOPs and QA documents	Task B	Within 10 business days of request by PO	1 copy - PO	

V. COPIES OF REPORTS SHALL BE SENT TO THE FOLLOWING ADDRESSES:

Address: Project Officer (PO)
Drug Development and Clinical Sciences Branch
Division of AIDS/NIAID/NIH
6700-B Rockledge Drive., Room 5153, MSC 7624
Bethesda, MD 20892-7624 (20817 for overnight deliveries)
E-mail address to be provided at time of contract award

Contracting Officer (CO)
Office of Acquisitions
Division of Extramural Activities/NIAID/NIH
6700-B Rockledge Dr., MSC 7612
Bethesda, MD 20892-7612 (20817 for overnight deliveries)
E-mail address to be provided at time of contract award

CLINICAL PHARMACOLOGY QUALITY ASSURANCE AND QUALITY CONTROL
RFP NIH-NIAID-DAIDS-08-14

APPENDIX A - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS
FORMAT FOR: TECHNICAL PROPOSAL – TABLE OF CONTENTS

It is strongly recommended that offerors use the following template as the Table of Contents for the technical proposal. All information presented in the technical proposal should be presented in the order specified below.

The following additional technical proposal instructions reflect the requirements of the RFP and are meant to provide additional instructions as well as a uniform format for technical proposals. The information requested in these instructions should be used as a guide for formatting and preparing the proposal. Offerors should follow the instructions in Section L of the solicitation, and include the information requested in this appendix.

Offerors are advised to give careful consideration to the statement of work, all reference material, appendices and attachments, the technical evaluation criteria, and the RFP as a whole, in the development of your proposal.

Offerors who propose subcontracts to perform portions of the statement of work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration between the prime and subcontractor(s), and the expected advantages of such an approach.

Offerors are reminded that the total page limitation for the technical proposal package is 250 pages, including all appendices and attachments.

Pages in excess of the limit will be removed and will not be read, evaluated or considered in the technical review.

Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1

I. PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identification if the proposal is an original or copy.
II. PROJECT OBJECTIVE, NIH FORM 1688
III. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
IV. TABLE OF CONTENTS
V. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)

SECTION 2 MANDATORY QUALIFICATION CRITERIA

This solicitation includes Mandatory Qualification Criteria, **which are specified in Section M of this solicitation. The Mandatory Qualification Criteria must be met at the time of the original technical proposal submission**. If the offeror fails to meet these criteria at the time of the submission, the proposal shall not be considered further for award.

SECTION 3 TECHNICAL APPROACH

A. PT Program

1. Discuss plans and operating procedures for providing Sites with PT samples, providing Sites with instructions regarding the PT samples, retrieving and analyzing PT data and reporting results. Provide a listing of drugs that the planned PT will cover.

2. Discuss plans and operating procedures for providing assistance to Sites whose PT results deviate from acceptable values. Include plans and timelines for re-testing Sites after implementation of corrective action.

B. Assay Development, Validation, and Implementation

1. Discuss plans and operating procedures for providing Sites with QC samples for assay development and validation, and for providing Sites with instructions regarding the QC samples.

2. Discuss plans and operating procedures for reviewing and evaluating AVRs prepared by Sites. Provide a listing of assay development and validation protocols or reports you have previously developed. Provide a listing of AVRs previously submitted to the FDA.

3. Discuss plans and operating procedures for transferring and implementing validated assay methods from the offeror to Sites. List the assay transfer protocols you previously developed. Provide an example of a draft agreement between you and a third party who provided confidential information on materials for the development of pharmacology assays.

4. Discuss plans and operating procedures for providing Sites with QC samples for monitoring the overall quality of assay implementation, and providing Sites with instruction regarding the QC samples.

5. Provide a listing of standard operating procedures (SOPs) and QA documents for assay development, validation/re-validation and implementation, as well as those for pharmacology specimen collection, sample handling, processing and storage for drug assays.

C. Acquisition, Characterization, Storage, Documentation, and Disbursement of QC Materials

1. Acquisition of ARGS/Reference Drug Powder, and QC reagents

    a. Discuss plans and operating procedures for acquiring AGRS/reference drug powder and QC samples/reagents from commercial and non-commercial resources. Describe the source of AGRS/reference drug powder and QC samples/reagents previously purchased. Provide a listing of AGRS/reference powders and other QC materials/reagents you previously purchased for specified projects, with sample copies of COAs that certify AGRS/reference drug powder you previously obtained.

    b. Discuss plans for compliance with applicable domestic and international regulations on the use of chemical hazardous agents and on the use of human tissue samples, and with HIPAA and Privacy Act requirements.

2. Characterization of ARGS/Reference Drug Powder, and Preparation of PT and QC samples

    a. Discuss your ability to determine characteristics and stability of AGRS/reference drug powder, and to prepare PT and QC samples.

    b. Describe what tests you might use and the timeline to characterize, certify and recertify AGRS/reference drug powder for projects specified in the SOW.

3. Determination of Stability of PT and QC Samples, and Reagents

Discuss your ability and studies you might perform to determine the stability of PT and QC samples and reagents.

4. Storage of ARGS/Reference Drug Powder, PT and QC Samples and Reagents

    a. Discuss your ability to securely store ARGS/reference drug powder, PT and QC samples, and reagents.

    b. Discuss the length of storage time, storage temperature, and shipping temperature of these materials.

    c. Provide a sample log that you previously used that describes composition, concentration, and type of matrix of PT and QC samples.

5. Shipment of ARGS/Reference Drug Powder, PT and QC Samples, and Reagents

    a. Discuss plans and operating procedures to ship AGRS/reference drug powder, PT and QC samples, and reagents to US and non-US destinations under appropriate shipping conditions (e.g. in dry ice or with temperature monitoring), and in accordance with IATA/ICAO dangerous goods shipping regulations and other relevant shipping regulations.

    b. Include documentation of the required licenses and permits, or include plans to obtain them prior to contract award date.

D. Training

1. Describe your experience, expertise, and competence for planning, organizing, and performing training workshops in the area related to PT and the development, validation and implementation of assays.

2. Describe how you would certify trainees after training; and

3. Describe how you would assess and evaluate the results of training.

E. Laboratory Inspections and Audits

1. Describe how you would conduct a laboratory inspection and how you would conduct an on-site audit for a particular study.

2. Describe how you would monitor and evaluate the ongoing and overall quality of the testing process (pre-analytical, analytical, and post-analytical) of a study or Site.

3. Describe how you would report the findings and deviations, and take corrective actions. Provide a sample checklist of items (deficiencies) that you might look for during an inspection.

F. Dissemination of PQA/QC Technical and Scientific Data

1. Describe proposed plans and approaches for preparing materials/reports in support of documents for IND/NDA submissions, and of scientific manuscripts for publication in peer-reviewed journals.

2. Describe proposed plans and approaches for preparing and presenting data at NIAID-sponsored meetings, and at US and non-US scientific meetings.

3. Describe how you would communicate with Sites working on PQA projects to discuss the work to be performed, workload and accomplishment, to review progress, and to investigate and resolve problems.

SECTION 4: PROJECT MANAGEMENT AND PERSONNEL

A. Identify the context of the project within the organization, its mission, and within the organizational portfolio of ongoing and historical activities. Offerors shall describe how projects in general are prioritized within their organization and the level of priority this contract shall receive. Document prior success in the timely completion of tasks done under Government-funded projects of similar nature to the PQA/QC

B. Provide a plan for project organization and management in relation to the implementation, conduct, monitoring and completion of the tasks identified in the Statement of Work. Propose time schedules for achieving contract objectives, and procedures for maintaining QC over the implementation and operation of the contract, including plans to keep within budget.

C. Describe the responsibilities and level of effort for all proposed personnel who will be assigned to the contract and an administrative framework indicating clear lines of authority and responsibility for personnel. A subcontract may be proposed for obtaining statistical expertise. Describe the extent to which outside consultants will be used, as well as assurance of their availability.

D. Document the education, training, relevant experience, accomplishments, full qualifications, and role of all proposed staff of the Offeror and any proposed subcontractors. Limit CVs to 2-3 pages. Describe in detail the qualifications of the two Key Personnel, the Principal Investigator and the Project Manager.

SECTION 5 SAFETY AND HEALTH

Provide plans and operating procedures for the safe handling of potentially hazardous biological specimens, in particular blood borne pathogens such as HIV, HCV. This includes:

A. A summary of your safety and health operating procedures manual;

B. Training certificates from Transport of Dangerous Goods training courses for key personnel;

C. Documentation of ongoing programs and plans for programs for adequate training of personnel handling infectious biological material, and

D. Evidence of training and compliance with applicable guidelines or regulations for a Biosafety Level 2 facility.

SECTION 6: FACILITIES, EQUIPMENT, **AND RESOURCES** (SOW Tasks C and G)

A. Document the availability, adequacy, security of facilities, equipment, work space, storage, space and other resources, including identification and description of support resources that will be required to carry out the SOW for the duration of the contract, including:

1. a description of the location and features of facilities, including clinical facilities, analytical and bioanalytical facilities, and computer facilities. Provide lease or ownership information;

2. a description of the location and features of bioresearch monitoring and bioresearch training resources;

3. a list of equipment, equipment maintenance plans and backup equipment, and

4. proof of CLIA certification and of most recent re-inspection, and a copy of the most recent cGLP inspection report of the facilities (by the FDA or by a state regulatory agency) and the offeror's response to that report.

B. Computerized Systems

1. Computerized Data Management Systems

   Describe the proposed software system(s) to capture and track data relating to the tasks described in Statement of Work. Include plans to design any software to be used to capture or analyze data in a format that will easily permit further development and inclusion in the LDMS®, should the assays be implemented in clinical trials and performed on patient specimens. The LDMS® will be part of the Government Furnished Property.

2. System Security

   Provide proposed plans for ensuring compliance with NIH requirements for computer system security. Additional information is also available at: http://irm.cit.nih.gov/security/sec_policy.html.

3. DAIDS Enterprise System Interface

   Describe proposed plans for interfacing with the DAIDS Enterprise System (see Appendix C) for transfer of data specified in the Statement of Work.

4. System Maintenance and Upgrades

   a. Describe proposed plans to maintain and upgrade software programs that are compatible with current software in use at NIAID and with changes made in NIAID systems.

   b. Describe proposed plans to maintain and upgrade reliable and secured electronic communication linkages with NIAID and Sites that facilitate sending e-mail and sharing text and data files.

5. InfoSec

   Provide a proposed plan to conduct a study of the InfoSec requirements of the entire project including: physical and electronic security for both hardware, software and communications, and whether all participants in the contract (subcontractors, NIAID staff, study Site investigators, etc.) need to have a secure capability for communication and exchange of information in the case of a national disaster that may disrupt the ability to interact and exchange needed information. Describe how you will protect data against loss.

6. IT Report

   Provide a proposed draft report of the IT requirements (with a complete IT security assessment), including identification of personnel assigned to interact with NIAID IT staff.

SECTION 7. TRANSITION PLANS

A. Initial Transition

Describe your plan for transition of all PQA/QC-related materials from the existing PQA/QC Program, funded as part of a grant to the ACTG and to the IMPAACT networks, including reagents, stored AGRS, PT samples, QC samples, all data files and data systems. Describe the coordination efforts

required between the existing PQA/QC Program and the Offeror for the relocation tasks. Include plans for the conduct of ongoing operations and coordination with Sites for transition of the PQA/QC Program. Provide timelines for the transition that minimize disruption of the existing PQA Program, which requires sending PT samples to Sites every six months. For information regarding the existing PQA/QC Program, please refer to:

1. Holland, D. T., R. DiFrancesco, J. Stone, F. Hamzeh, J. D. Connor, and G. D. Morse. 2004. Quality assurance program for clinical measurement of antiretrovirals: AIDS clinical trials group proficiency testing program for pediatric and adult pharmacology laboratories. Antimicrob. Agents Chemother. 48:824-831.

2. DiFrancesco, R., D. T. Holland, J.E. Schiffhauser, B.L. Robbins, K.M. Tooley, and G. D. Morse. 2005. A quality assurance program for AIDS clinical trials group pharmacology studies. Qual Assur J. 9, 22-30.

B. Final Transition

Describe general plans for transition of the PQA/QC Program to a successor Contractor of all contract-related materials at the end of the contract period of performance.

SECTION 8: OPTION PLANS

For an expansion through the exercise of an Option, provide a proposed plan for staffing, facilities and other resources necessary to provide the services called for in the Statement of Work. The Plan should include the timelines for all tasks involved in initiating and implementing the Option, proposed modifications in organizational structure and staffing mix, coordination, management and QA procedures, and other Contractor functions that may be required to carry out expansions. If subcontractors are proposed, describe their proposed roles and responsibilities in providing services to additional US and non-US Sites.

Under an Option, the Contractor shall add one (1) Site to the PQA/QC Program. Sites will be added during contract years 2-7. The NIAID reserves the right to exercise more than one (1) option per year, however, the total number of 'optional' Sites shall not exceed six (6) during the 7-year period of the contract.

SECTION 9: TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

Section L of the RFP provides minimum documentation requirements for the following items. The required information described in Section L should be assembled together, in the following clearly marked sections of the technical proposal. Refer to Section L of the RFP for specific requirements. Also read each section, below, carefully. In some cases, offerors may be asked to provide documentation which is in addition to the minimum requirements identified in Section L.

A. Human Subjects

Section L of the RFP specifies the minimum documentation requirements for Human Subjects use. All related documentation should be included in the proposal in a clearly marked section. The Technical proposal should document all information necessary to evaluate Human Subject use. The following information is essential:

1. Include plans for compliance with applicable domestic and international regulations on the use of human subjects (e.g. IRB submission and approval plans, consent procedures, etc.). Also include, as applicable, documents relevant to the following:

   - Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (MARCH 2005)

- Instructions to Offerors Regarding Protection of Human Subjects
- Collaborating Site(s)
- Required Education in the Protection of Human Research Participants
- Inclusion of Women and Minorities in Research Involving Human Subjects
- Inclusion of Children in Research Involving Human Subjects
- Data and Safety Monitoring in Clinical Trials
- Research Involving Human Fetal Tissue
- Research Involving Prisoners as Subjects
- Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)
- Human Embryonic Germ Cell (HEGC) Research
- Human Embryonic Stem Cell (HESC) Research
- HIV Antiretroviral Treatment Trials

2. Health Insurance Portability & Accountability Act (HIPAA)

   Include plans for compliance with HIPAA.

B. Sharing Research Data (Plan)

Section L of the RFP specifies the minimum documentation requirements for Data Sharing. All related documentation should be included in the proposal in this clearly marked section. The Technical Proposal should include a plan for Data Sharing as required by this RFP.

C. Sharing of Model Organisms for Biomedical Research (Plan)

Section L of the RFP specifies the minimum documentation requirements for Model Organism sharing. All related documentation should be included in the proposal in this clearly marked section. The Technical Proposal should include a plan for sharing Model Organisms as required by this RFP.

D. IT Systems Security

Section L of the RFP specifies the minimum documentation requirements for IT Systems security. All related documentation should be included in the proposal in this clearly marked section. The Technical Proposal should include a plan for IT Systems security as required by this RFP.

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APPENDIX B - ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

In addition to the format requirements for the business proposal that are contained in Section L of the solicitation, the information provided in this appendix is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the statement of work, all reference material provided as appendices and attachments, and the technical evaluation criteria, and, the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your business proposal. Offerors should consider and include the information requested in this appendix, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVERSHEET

SECTION 2 – COST OR PRICE SUPPORT

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. In addition to a standard seven (7) year annual cost proposal, the offeror shall prepare a cost proposal per protocol that will be used. All related documentation should be included in the proposal in a clearly marked section.

SECTION 3 – UNIFORM COST ASSUMPTIONS

A. Technical Cost Assumptions

1. Proficiency Testing (SOW Task A): For estimating PT, the offeror shall assume two (2) rounds of PT executed annually executed at nine (9) US Sites and one (1) Site in Asia, each round consisting of:

    a. shipment of a panel of twenty coded PT samples (including duplicate samples and matrix control samples), 4-5 ml each in EDTA plasma; shipped in one-cubic foot boxes on dry ice, to nine (9) US Sites and one (1) Site in Asia, two (2) times/year. PT samples shall include: six (6) protease inhibitors at low (Code A), medium (Code B), and high (Code C) concentrations; three (3) non-nucleoside reverse transcriptase inhibitors at low (Code D), medium (Code E), and high (Code F) concentrations; and three (3) nucleoside reverse transcriptase inhibitors at low (Code G), medium (Code H), and high (Code I) concentrations; and two (2) matrix controls (Code J);

    b. HPLC-UV and HPLC-MS measurements performed on 60 coded PT samples (20 samples in triplicate) at the Offeror's site each round; and

    c. receipt of PT data from Sites, analysis and reporting of results.

2. Assay Development, Validation, and Implementation

    a. For estimating assay development studies described in Task B.1. of the Statement of Work, the offeror shall assume:

Shipment of 20 QC samples of the tested drug (such as integrase inhibitors), in human plasma, 0.5 ml/sample; shipped to two (2) Sites in the US three (3) times each year.

One (1) assay development study per year, including preparation and analysis of 200 QC samples and 800 representative samples of the assay development study, using an HPLC-UV assay.

b. For estimating assay validation studies described in SOW Task B.2, the offeror shall assume:

Shipment of a panel of 20 QC samples of the tested drug, 4-5 ml/sample in human plasma, for assay validation, to two (2) participating Sites in the U.S three (3) times each year.

One (1) assay validation study that will be conducted at the offeror's site each year; prepared and analyzed 200 QC samples and 800 representative samples of the assay validation study using HPLC-MS.

Four (4) AVRs submitted from participating sites to the Offeror; reviewed and evaluated.

c. For estimating assay implementation studies described in Task B.3.of the Statement of Work, the offeror shall assume:

Shipment of a panel of 20 QC samples of zidovudine, lamivudine, and lopinavir/ritonavir to four (4) Sites in the US for assay implementation studies, four (4) times each year;

Transfer of an HPLC-UV assay for the measurement of a protease inhibitor from the offeror's facility to one (1) Site in the US each year.

Writing four (4) SOPs for conducting assay validation studies each year.

3. For estimating acquisition, characterization, storage, documentation, and disbursement of QCM described in SOW Task C of the Statement of Work, the offeror shall assume:

a. Two (2) ARGS/reference drug powders and appropriate known QC standards/reagents purchased each year.

b. Conduct of two (2) identity and purity studies, and analysis of 250 representative samples of ARG/ reference drug powders each year.

c. Conduct of two (2) stability studies (e.g., freeze-thaw cycles and at 60^0C), and analysis of 250 representative samples of ARG/ reference drug powder, PT and QC samples will be analyzed each year.

d. Conduct of three (3) comparative studies of storage and shipment conditions (e.g., room temperature, -20^0C, and -70^0C) of PT and QC samples each year.

e. Storage of 1,500 analytical samples and 2,500 ml human plasma -20^oC, and 1,500 new samples at -70^oC each year.

4. For estimating Contractor's Site training services (SOW Task D), the offeror shall assume:

a. one hands-on training workshop each year, for two days with up to ten (10) participants per workshop, at the offeror's Site. The offeror will not be responsible for participant travel support.

b. Phone/email/web interactions with nine (9) US and one (1) non-US Sites four (4) times each year.

5. For estimating laboratory inspection and audits services (SOW Task E), the offeror shall assume one (1) on-site visit combining inspection and audit, conducted each year in one (1) US Site.

B. Information Resources

1. The Offeror shall assume the following minimum requirements for computer hardware and software to be provided by the Contractor:

   a. IBM Compatible computer (PC), with a processor speed of 2.5 GHz, 512 MB RAM, DVD+/-RW (Multi Format Double Layer Drive), 3.5" disk drive, 1.44MB disk drive, 80 GB hard drive, 15" LCD flat panel monitor, 10/100 32-bit Fast Ethernet card, 4 USB ports.

   b. Hewlett Packard (HP) Compatible Laser Jet Printer or other laser printer with USB port capability.

   c. Internet service provider and high speed connection to the internet (cable modem, DSL, ISDN, Ethernet).

   d. Software packages that include Microsoft Windows 2000 Professional or XP Professional, Microsoft Office Professional 2003 Suite, Symantec PC Anywhere-Version 11.5 or higher, Backup capability (examples: Colorado Backup, Iomega, CMS), anti-virus software with up-to-date virus definitions and on-going support for definition updates (e.g. McAfee, Norton Anti-virus, etc.).

2. The offeror shall assume the cost of complying with computer system security needs to meet NIH requirements and the cost of interacting with the DAIDS Enterprise System as described in Appendix C.

3. The offeror shall assume the cost to develop and maintain a PQA website.

C. Travel

For estimating purposes, the Offeror shall assume:

1. One (1) trip by one (1) Contractor person to Bethesda, Maryland for two (2) days each year to meet with the Project Officer.

2. One (1) trip by two (2) Contractor persons to a US Site for three (3) days each year, to conduct a laboratory inspection.

3. Attendance of one (1) Contractor person in one (1) meeting in the US of three (3) days duration each year, and attendance of one (1) Contractor person in a non-US meeting of five (5) days duration each year.

D. Equipment (GFP)

The offeror is expected to provide HPLC systems with UV and mass spectrometry, UV spectrophotometer, and other analytical instruments needed to conduct activities described in the Statement of Work. Equipment leasing costs, prorated for the actual use of the equipment on this Contract, may be charged to the Contract. Computer hardware and software, and computer facilities are to be provided by the offeror.

E. Transition Plans

The offeror shall bear the cost of planning and executing the initial transition and the final transition as described in items A. and J. of the Statement of Work.

F. OPTIONS

The offeror shall estimate the Option of adding one (1) new Site to the PQA/QC Program, providing services described in Section K of the SOW. The offeror shall include the cost of additional required staff, facilities and other resources necessary to exercise the Option:

1. Proficiency Testing;

2. AGRS/reference drug powder and QC samples for the development, validation and implementation of assays; and

3. Training.

G. Other

Assume inspection and audit of the offeror's facilities once every two (2) years by a regulatory agency as required by CLIA and cGLP regulations.

SECTION 4 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

A. Small Business Subcontracting Plan

Section L of the RFP specifies the minimum documentation requirements for completing a subcontracting plan. This plan should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

B. Extent of Small Disadvantaged Business Participation

Section L of the RFP specifies the minimum documentation requirements for small disadvantaged business utilization. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

C. Past Performance Data, including references

Section L of the RFP specifies the minimum documentation requirements for providing past performance information. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

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APPENDIX C - ADVANCED UNDERSTANDINGS

A. Confidentiality of Information

Information and data provided to or generated by the Contractor under this contract shall be treated confidentially and protected by an Advanced Understanding to be included in the resulting contract and worded as follows: "Because there is a likelihood that the Contractor will be utilizing and evaluating pharmaceutical compounds and bioanalytical methods provided to the Government by third party suppliers (commercial, non-commercial, and research resources), it is essential to include provisions that will protect the proprietary rights of the suppliers. Whenever these materials and methods generally are provided to the Government as proprietary and confidential, the Contractor shall be bound by the same terms and conditions as the Government in these agreements, with respect to the proprietary and confidential nature of the information provided by the laboratory. All information provided by the supplier or Project Officer shall be assumed to be confidential unless specifically identified as non-confidential in writing by the Project Officer. Confidential information may not be revealed without written permission. All materials and methods supplied to the Contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these materials will be permitted.

All other data provided to the Contractor under the contract similarly are to be considered confidential. All data provided to the Contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these data will be permitted. Any manuscript or scientific meeting abstract generated under this contract must be submitted for review and written approval by the Project Officer before submission for public presentation or publication. Contract support shall be acknowledged in such publications. A "publication" is defined as an issue or printed material offered for distribution or any communication or oral presentation of information. The Project Officer will review all manuscripts/abstracts in a period of time not to exceed 20 calendar days from receipt, and will either grant clearance for publication/disclosure, recommend changes, or, as applicable, refer the document to the supplier of the materials and methods for their review. When the supplier does not consent to publication of the manuscript or abstract, the Project Officer shall withhold approval to publish in accordance with the terms and conditions of any existing Agreement between NIAID and the Contractor, or the laboratory. NIAID will use its best efforts to assist and expedite the review and approval process by the supplier and laboratories."

Shall patents arise from this contract, they will be subject to laws governing federally funded invention. The Government retains, for government purposes, a non-exclusive, irrevocable, paid-up license to federally funded inventions."

B. Secure One HHS

"HHS is responsible for implementing a Department-side information security program to assure that each information system and associated facility provides a level of security that is commensurate with the risk and magnitude of the harm that could result from the loss, misuse, disclosure, or modification of information contained in the system. Each system's level of security shall protect the confidentiality, integrity, and availability of the information and comply with all security and private-related laws and regulations. The HHS Information Security Program Policy and Handbook, known as 'Secure ONE HHS', provide baseline security policies for the Department. These policies apply to the Department, which includes Operating Division (OPDIV) and Staff Division (STAFFDIV) personnel, Contractors, and other authorized users. All information technology related issues such as technical security, information security, personnel security, web management, implementation management, database management, electronic communications, electronic reporting, etc., defined within this RFP is subject to the prescribed methods defined within 'Secure ONE HHS.' The Contractor shall provide a description of a security program that is in place in the Contractor's facility that will assure compliance

with 'Secure ONE HHS,' and describe any other components of your security system used to keep data and access to it, secure."

C. Computerized Systems

During the contract period of performance, the NIAID may have a need to convert existing systems, databases, and applications to a functionally equivalent and compatible environment. These Advanced Understandings apply to the computerized systems described below.

1. LDMS® and Data Management Center

Most Sites are currently linked through LDMS®, an electronic network which is used to manage PQA/QC specimens, assign pharmacokinetic assays, create the panel number, sample code, round number and date for the proficiency panel, batch numbers, specimen time, and number of tubes and aliquots; create storage reports, diskette and shipping and email files to a remote Data Management Center. The LDMS® is maintained and updated by Frontier Science Technology and Research Foundation (www.fstrf.org), the data center for two large clinical trial networks.

DAIDS anticipates that software requirements will change over the course of the 7-year contract and that another software program will replace the LDMS®. When that occurs, the offeror will be required to use software that provides continued support to Sites participating in the PQA Program.

2. DAIDS Enterprise System (DAIDS-ES)

Successful offerors may be required to provide some Contractor-related information through the DAIDS-ES. While some of this may be accomplished through a link from DAIDS-ES to the Contractor's website, some data may need to be shared by the Contractor, with DAIDS-ES, in which case data sharing agreements, standards, etc., will be required.

The DAIDS-ES is a comprehensive system that supports the business functions, management and oversight responsibilities of the Division of AIDS. The current components of the DAIDS-ES include:

a) DAIDS Master Contact System

The DAIDS Master Contact System is a centralized system for all address and contact information for stakeholders engaged in clinical research, such as investigators, participating institutions, laboratories, agencies, pharmaceutical sponsors, manufacturers, etc.

b) DAIDS Expedited Adverse Event Reporting System (DAERS)

The DAERS is a web-based implementation for expedited reporting of adverse events in DAIDS-sponsored clinical trials. DAERS is a 21 CFR Part 11 compliant system for use in therapeutic, vaccine and prevention trials.

c) DAIDS Protocol Management System

The DAIDS Protocol Management System supports end-to-end clinical trials processes, including: protocol development, registration, conduct, accrual, oversight, Site monitoring, tracking and closeout. The system is CDISC and HL7 compliant with full auditing capabilities.

Successful Offerors may be required to interface, integrate or adapt their information system(s) to interact with these and future components of the DAIDS-ES, as necessary. To achieve compatibility, DAIDS and its collaborators (Contractors, cooperative agreement holders, grantees,

etc.) will implement applications or data exchange mechanisms using platform technology standards such as: Web Services, eXtensible Markup Language (XML), XML Schema Definitions (XSD), RDBMS, NET Framework, UDDI, IIS, Internet Explorer, Service Oriented Architecture (SOA), Design Patterns, Frameworks and Templates as defined by the DAIDS-ES. Collaborators shall adhere to these guidelines and standards on a continual basis.

This requirement will include the need to utilize DAIDS-ES-specified software Application Programming Interfaces (APIs) or XML and XSD, where appropriate, in all relevant implementations that affect specific types of transactions, Graphical User Interfaces (GUI) and other software-based tasks that interact with or become part of the DAIDS-ES.

Depending upon the architecture and implementation of Offerors' data management system(s), the following activities may be required to be compatible with the DAIDS-ES:

d) Build Interface

Using DAIDS-ES–specified data standards, collaborators shall provide access to data in their local system(s). Standards shall either be industry data exchange standards such as those specified by NIH, CDISC, HL7 or adapted versions of there as defined by DAIDS.

e) System Adaptation

Collaborators may need to adapt or modify their data management system(s) to receive and store data from the DAIDS-ES. Collaborator's data system(s) may have to be adapted or modified to accommodate the DAIDS standards.

f) System Integration

Collaborators may be required to dynamically obtain data from the DAIDS-ES to perform specific job functions. This will require the integration of collaborator's system(s) with the DAIDS-ES via data linkages using the appropriate latency factor or through Web Services. For example, the DAIDS-ES will serve as a central repository for investigator, laboratory, assays and protocol status information. Collaborators whose work requires information from the DAIDS-ES must dynamically integrate it into their respective data systems(s).

The NIAID may have a requirement within the period of the awarded contract to convert existing systems, databases, and implementations to a functionally equivalent and compatible environment.

D. Intellectual Property

Contractors acknowledge that:

- If needed for the project, the Contractor is solely responsible for the timely acquisition of any proprietary rights, including intellectual property rights, and all materials appropriate for the Contractor to perform the project.

- Prior to, during, and subsequent to the award, the US Government is not required to obtain for the Contractor any proprietary rights, including intellectual property rights, or any materials needed by the Contractor to perform the project.

- The requirement to report to the US Government all inventions made in the performance of the project, as specified at 35 USC. Sect. 202 (Bayh-Dole Act).

- The Contractor is encouraged to reach early consensus with any proposed partners regarding any appropriate intellectual property or other legal issues that may arise during the project. In addition, Contractors are expected to exercise their Bayh-Dole rights in a manner that does not

conflict with the goals of this award or the intent of the Bayh-Dole Act to promote the utilization, commercialization and availability of US Government-funded inventions for public benefit. Finally, the Contractor is expected to make new information and materials known to the research community in a timely manner through publications, web announcements, and reports to the NIAID or other mechanisms consistent with laws, regulations, and NIH policies.

E. Intellectual Property Option to be Offered to NIAID's Third Party Providers of Proprietary Material and Protection of Resultant Proprietary Data

This article must be included in any subcontract for evaluation of materials and methods. The subcontractor shall then have all the obligations of the Contractor.

The goal of this contract is to promote the development of critical biological information by evaluating various materials for anti-microbial activity. For the purposes of this agreement, "material" includes compositions of matter, and associated information such as "methods" of making or using the compositions. It is expected that the great majority of materials will be proprietary to third parties. It is clear from the NIAID's experience that third party providers ("provider") will not provide their proprietary material ("Material") without assurance that the intellectual property rights associated with their Materials will be protected. Accordingly, to encourage providers to provide their Materials for evaluation under this contract, the Contractor agrees to the Article pertaining to the Intellectual Property Option to the Provider, which requires the Contractor and its subcontractors to provide a research use license and a commercialization license option to Subject Inventions made under the contract to the Providers as follows:

The Contractor agrees to promptly notify the NIAID and the provider in writing of any Subject Inventions of the Contractor and/or any other employees or agents of the Contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of work under this contract using a Provider's Material (hereinafter "Contractor Invention"). The notice shall inform the Provider(s) of its right to the option set forth herein. This may be accomplished by attaching a copy of the Article to the notice.

1. Single Provider

With respect to Contractor inventions resulting from the use of Material provided by one provider, the Contractor agrees to grant to the provider: (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (ii) a time-limited first option to negotiate an exclusive, world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to any Contractor Invention on terms to be negotiated in good faith by the provider and the Contractor, subject to the following conditions:

The Contractor will allow provider three (3) months from the date the Contractor sends written notice to the provider of the existence of a Contractor invention (or such additional period as the provider and the Contractor may agree) to notify the Contractor in writing, whether or not it wants to obtain an exclusive license to the Contractor invention. If the provider fails to notify the Contractor in a timely fashion then the Contractor's obligation to offer the provider a license option with respect to that Contractor Invention will expire and the Contractor will be free to dispose of its interests in such Contractor Invention in accordance with the Contractor's policies. If the Contractor and the provider fail to reach agreement within 90 days, (or such additional period as the provider and the Contractor may agree) on the terms for an exclusive license for a particular Contractor Invention, then for a period of six (6) months thereafter the Contractor will not offer to license that Contractor Invention to any third party on materially better terms than those last offered to the provider without first offering such terms to the provider, in which case the Contractor will offer the provider a period of 30days in which the provider can accept or reject the offer.

2. Multiple Providers

With respect to a Contractor invention resulting from the use of Materials provided by multiple providers, but which is an improvement only to a Material of a specific provider, the Contractor agrees to grant to that provider the rights described above in (1).

With respect to any Contractor inventions resulting from the use of Material from multiple providers, but that are not improvements to or specific to a single Material, the Contractor agrees to grant to each provider who provided Material: (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (ii) a time-limited first option to negotiate a co-exclusive, world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all such Contractor inventions on terms to be negotiated in good faith by each provider and the Contractor subject to the following conditions:

The Contractor will allow each provider three (3) months from the time the provider is sent written notice by the Contractor of the existence of a Contractor invention (or such additional period as each provider and the Contractor may agree) to notify the Contractor, in writing, whether or not the provider wants to obtain a co-exclusive license to the Contractor invention. If a provider fails to notify the Contractor, in a timely fashion then Contractor's obligation to offer that provider a license option with respect to that Contractor invention will expire and the Contractor will continue to offer an option to a co-exclusive license to the other providers as set forth herein. If there is a single other provider, it shall be offered an option to an exclusive license as though it were a single provider. If no provider notifies the Contractor in a timely fashion, the Contractor will be free to dispose of its interests in such Contractor invention in accordance with the Contractor's policies.

3. Provider Inventions

The Contractor agrees that notwithstanding anything herein to the contrary, any invention or discovery, whether patentable or not, which is not a Subject Invention as defined in **35 USC 201(e)**[1] but arises out of an intentional and unauthorized use or modification of the Provider's Material by the Contractor and/or any other employees or agents of the Contractor, will be the property of the provider (hereinafter "Provider Invention"). The Contractor will promptly notify the provider in writing of any such Provider Inventions and, at the Provider's request and expense, the Contractor will cause to be assigned to the provider all right, title and interest in and to any such Provider Inventions and give provider any assistance reasonably necessary to obtain patents (including causing the execution of any invention assignment or other documents). The NIAID recognizes that the Contractor may also be conducting other research using the provider's Material under the authority of a separate agreement with the provider during the term of this contract; any invention arising under such separate agreement will not be subject to the terms of this provision entitled, **"Provider Inventions."**

4. Protection of Proprietary Data

All Materials, data and other information supplied by the provider or the Project Officer shall be assumed to be confidential unless specifically identified as not confidential in writing by the Project Officer. The Contractor agrees that its principal investigator and/or any other employees or agents of the Contractor will provide the data generated under this contract exclusively to the NIAID or if directed by the NIAID, to the provider and the FDA or other appropriate Federal regulatory agencies. The Contractor understands that the NIAID must negotiate individual agreements with the various providers to obtain Materials and that the terms of the agreements may vary. The NIAID intends that these agreements will provide for the Contractor's right to publish results generated by the Contractor under this contract after a reasonable period of time to allow the provider to file patent implementations and to protect its proprietary information. The Contractor agrees to enter into confidentiality agreements with providers when required by the

providers as a condition for the Contractor to receive Materials. Such agreements shall reference this contract by contract number and shall be consistent with any agreement the NIAID has entered into with the provider to obtain Materials. In the event the Contractor reasonably objects to the terms of the confidentiality agreement, the Contractor shall promptly bring such objection to the attention of the Contracting Officer for an appropriate resolution.

35 USC 201(e): The term "Subject Invention" means any invention of the Contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7 USC. 2401(d)) must also occur during the period of contract performance.